Responder™ 2000

defibrillator/monitor

Operator's Manual

2026116-001 Revision B
English

REVISION HISTORY

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SECTION 1: INTRODUCTION

OVERVIEW

This operator's manual provides instructions for the safe and proper operation, as well as set-up, configurations, and maintenance information.

Be sure to familiarize yourself with the operation of the Responder 2000 prior to its use.

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PRECAUTION: Federal law restricts this device to be sold by or on the order of a physician or practitioner licensed by state law in which he/she practices to use or order the use of the device.

RESPONDER 2000 DESCRIPTION

The Responder 2000 is a defibrillator/monitor/pacemaker intended for use by personnel trained in its operation. The device is lightweight, portable, easy to use and reliable. It incorporates a 320 x 240 transmissive color TFT color display for wide viewing angles in all light conditions. The device operates using either an AC power supply or internal rechargeable Li-Ion battery. The device provides continuous ECG monitoring and three types of therapies: defibrillation, cardioversion and external pacing. Defibrillation can be applied manually or semi-automatically. Pacing therapy can be either fixed or demand. The device employs patented RHYTHMx® software which provides ECG rhythm analysis. STAR® Biphasic waveform delivers impedance-compensated energy ranging from 2-270 Joules. Features and options include external paddles, spoons, disposable pads, 3- and 5-lead ECG, pulse oximetry (SpO_2), built-in 60 mm thermal printer, internal storage of event history and remote synchronization to bedside monitor.

The Responder 2000 is suitable for indoor use only. It is not intended for use in vehicles or aircrafts.

INDICATIONS FOR USE/INTENDED USE

The Responder 2000 defibrillator system is intended to be used by personnel who have been trained in its operation.

The Responder 2000 is indicated for the termination of certain fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Delivery of energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and in relatively stable patients, ventricular tachycardia.

The semi-automatic advisory mode is for use in cardiac arrest in patients of at least 8 years of age. The patient must be unconscious, pulseless, and not breathing spontaneously before using the defibrillator to analyze the patient's ECG rhythm.

The Responder 2000 3-lead and 5-lead ECG monitoring allows for identification or interpretation of cardiac rhythms or dysrhythmias and calculation of heart rate.

The Responder 2000 noninvasive pacing as a therapy is indicated for patients with symptomatic bradycardia or asystole.

The Responder 2000 pulse oximetry is intended for the continuous external monitoring of arterial oxygen saturation and pulse rate and is indicated for use in any patient who is at risk of developing hypoxemia.

CONTRAINDICATIONS FOR USE

CONTRAINDICATIONS FOR MANUAL DEFIBRILLATION THERAPY

Asynchronous defibrillation therapy is contraindicated in patients that exhibit one or any combination of the following:

- Responsive
- Spontaneous breathing
- Palpable pulse

CONTRAINDICATIONS FOR SEMI-AUTOMATIC THERAPY

The semi-automatic shock mode is not be used on patients that exhibit one of any combinations of the following:

- Responsive
- Spontaneous breathing
- Palpable pulse
- Less than 8 years of age or 55 lbs. (25kg). Therapy should not be delayed to determine patient's exact age or weight.

CONTRAINDICATIONS FOR NONINVASIVE PACING THERAPY

Noninvasive pacing is contraindicated in the treatment of ventricular fibrillation. Noninvasive pacing in the presence of severe hypothermia may be contraindicated.

SAFETY TERMS AND CONDITIONS

The following is a list of Responder 2000 safety alerts that appear in this section and throughout this manual. You must read, understand, and heed these safety alerts before attempting to operate the Responder 2000.

The signal words shown below identify the potential hazard categories. The definition of each category is as follows:

DANGER: This alert identifies hazards that will cause serious personal injury or death.

WARNING: This alert identifies hazards that may cause serious personal injury or death.

PRECAUTION: This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

NOTE: Notes contain additional information on usage.

DANGERS

DANGER: Fire and Explosion Hazard
Do not operate the Responder 2000 in the presence of flammable gases (including concentrated oxygen) to avoid possible explosion or fire hazard.

WARNINGS

WARNING: The Responder 2000 is restricted to a single patient at a time.

WARNING: Shock Hazard
Defibrillation shock current flowing through unwanted pathways is potentially a serious electrical shock hazard. To avoid this hazard during defibrillation abide by all of the following:

- Do not touch the patient
- Do not touch conductive fluids such as gel, blood, or saline
- Do not touch metal objects in contact with the patient such as a bed frame or stretcher
- Keep defibrillation pads and ECG electrodes clear of other pads or metal parts in contact with patient
- Disconnect all equipment that is not defibrillator proof from the patient before defibrillation

WARNING: Shock Hazard
Do not immerse any portion of this device in water or other fluids. Avoid spilling fluids on device or accessories. Do not clean with flammable agents. Do not autoclave or sterilize this device or accessories unless otherwise specified.

WARNING: Shock Hazard
Do not disassemble the Responder 2000! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to authorized service personnel.

WARNING: Shock Hazard
Do not use the Responder 2000 on a conductive surface, including any wet surface.

WARNING: The Responder 2000 is not intended to be deployed in settings or situations that promote use by untrained personnel. Operation by untrained personnel can result in injury or death.

WARNING: When transporting the Responder 2000, it is important to position it with the display facing away from the body. If not, the buttons or Rotary Selector Knob may be bumped and inadvertently moved from its current position.

WARNINGS (CONTINUED)

WARNING: Remain attentive to the patient during the delivery of therapy. Delay in delivering a shock may result in a rhythm that was analyzed as shockable converting spontaneously to non-shockable and could result in inappropriate delivery of a shock.

WARNING: Do not use batteries, pads, cables, or optional equipment other than those specified by GE Healthcare. The use of unapproved equipment may cause the Responder 2000 to function improperly during a rescue.

WARNING: Adjacent and/or Stacked Equipment
The Responder 2000 should not be used immediately adjacent to or stacked on top of other equipment. If adjacent or stacked use is necessary, the Responder 2000 should be observed to verify normal operation in the configuration in which it will be used.

WARNING: Responder 2000 Disposal with Battery
Disposal of the Responder 2000 with the battery inserted presents a potential shock hazard.

WARNING: Responder 2000 Disposal Contamination
To avoid contaminating or infecting personnel, the environment, or other equipment, make sure you disinfect and decontaminate the Responder 2000 appropriately prior to disposal.

WARNING: Do not allow pads to touch each other, ECG electrodes, lead wires, dressings or transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillating energy away from the heart muscle. See Section 3 for correct usage.

WARNING: Pacemaker Patients
Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest for some arrhythmias. Do not rely entirely upon rate meter alarms. Keep pacemaker patients under close surveillance. See this manual for disclosure of pacemaker pulse rejection capability of this instrument.

WARNING: For treatment of patients with implantable devices such as permanent pacemakers or cardioverter defibrillators, consult a physician and the instructions for use provided by the device's manufacturer.

WARNING: The use of accessories and cables other than those specified may result in increased electromagnetic emissions or decreased immunity of the equipment.

WARNING: The Responder 2000 should not be stored with the battery inserted. Remove the battery from the Responder 2000 when storing the device.

WARNING: A protective ground connection by way of the grounding conductor in the power cord is essential for safe operation. To avoid electrical shock, plug the power cord into a properly wired receptacle, use only the power cord supplied with the device, and make sure the power cord is in good condition.

WARNING: If the integrity of the external power earth conductor arrangement is in doubt, unplug the device from the mains AC and operate it from a Responder 2000 rechargeable battery that is charged.

WARNING: The Responder 2000 will not power on if AC power is lost when the battery is low or not inserted in the Responder 2000.

WARNING: Due to the unique impedance characteristics of the patient, the Responder 2000 may not be able to shock the patient.

WARNING: Pads should be kept clear of other ECG electrodes or metal parts in contact with the patient.

WARNING: Defibrillation may cause implanted electrical devices (i.e., pacemakers, infusion pumps) to malfunction. Do not place pads over implanted electrical devices. Check implanted device function after defibrillation.

WARNINGS (CONTINUED)

WARNING: When the patient is a child under 8 years of age or weighs less than 55 lbs (25kg), the Responder 2000 should be used with pediatric defibrillation pads. Therapy should not be delayed to determine the patient's exact age or weight. The Responder 2000 does not select the energy or shock sequences based on the defibrillation pads connection.

WARNING: Use demand mode pacing whenever possible. Use fixed mode pacing when motion artifact or other ECG noise makes R-wave detection unreliable or when ECG monitoring electrodes are not available.

WARNING: Do not rely solely on SpO_2 readings; assess the patient at all times. Inaccurate measurements can be caused by:

- Incorrect sensor application or use.
- Significant levels of dysfunctional hemoglobins (such as carboxyhemoglobin or methemoglobin)
- Injected dyes such as methylene blue, or intravascular dyshemoglobins such as methemoglobin or carboxyhemoglobin
- Exposure to excessive illumination such a surgical lamps (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight.)

WARNING: Failure on the part of all responsible individuals, hospitals, or institutions, employing the use of Responder 2000, to implement the recommended maintenance schedule may cause equipment failure and possible health hazards. The manufacturer does not, in any manner, assumes the responsibility for performing the recommended maintenance schedule. The sole responsibility rests with the individuals, hospitals, or institutions utilizing the Responder 2000.

WARNING: After the visual inspection, if the Responder 2000 and/or its accessories are damaged please contact Customer Service. The Responder 2000 will need to be returned for repair. The accessories should be disposed of appropriately and replacement parts shall be ordered.

WARNING: Cleaning liquids: DO NOT submerge the device in liquids or pour cleaning liquids over, into or onto the device.

WARNING: Do not trigger more than five (5) consecutive test discharges (or internal safety discharges) within thirty (30) minutes.

WARNING: Do not disassemble the Responder 2000! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to authorized service personnel.

WARNING: Electrode performance may be adversely affected by pre-attaching, storing with defibrillator cable, or exposure to air for long periods of time. These electrodes are not recommended for electrosurgery.

WARNING: Defibrillating a patient with normal heart rhythm may induce ventricular fibrillation.

WARNING: Position the patient flat on a hard surface where he/she is electrically insulated. The patient must not be allowed to come into contact with metal parts, e.g., bed or liner, to prevent unwanted pathways for the defibrillation current which may endanger the assistants. For the same reason, do not position the patient on wet ground (rain, accident in swimming pool).

WARNING: The patient's chest must be dry, because moisture can cause unwanted pathways for the defibrillation current.

PRECAUTIONS

PRECAUTION: Storage of batteries at elevated temperatures will significantly reduce capacity. It is recommended that batteries be stored and recharged only at room temperature, about 21°C. In any case, do not exceed 50°C.

PRECAUTION: Temperature/Humidity/Pressure Extremes
Exposing the Responder 2000 and battery to extreme environmental conditions outside of its specified parameters may compromise the ability of the Responder 2000 and battery to function properly.

PRECAUTION: Recycle or dispose of the lithium-ion battery in accordance with your country's regulations. To avoid fire and explosion hazard, do not burn or incinerate the battery.

PRECAUTION: Prior to disposal, remove the batteries from the Responder 2000. Then dispose of the device in accordance with your country's regulations for equipment containing electronic parts.

PRECAUTION: Dispose of the pads or electrodes in accordance with all federal, state and local laws.

PRECAUTION: Federal law restricts this device to be sold by or on the order of a physician or practitioner licensed by state law in which he/she practices to use or order the use of the device.

PRECAUTION: Do not use pads that are damaged or expired. This may result in improper Responder 2000 performance.

PRECAUTION: Viewing the Responder 2000 display, LEDs, and flashing buttons may cause seizures in individuals prone to this condition.

PRECAUTION: Avoid excessive mechanical shock to the Responder 2000.

PRECAUTION: The Responder 2000 attached cables may cause a trip hazard while cables are attached to the Responder 2000.

PRECAUTION: Electrosurgery equipment may cause interference in the Responder 2000 if operated on or nearby the patient. Disconnect Responder 2000 from the patient before using electrosurgery equipment.

PRECAUTION: The use of any pads may irritate the skin or cause an allergic reaction. If skin irritation develops, change the location of pads. The affected area can be treated with a topical ointment, according to patient care protocols for skin irritations. If a severe allergic reaction occurs, discontinue use.

PRECAUTION: The pads must not be used if:
The packaging has been damaged
The expiration date has passed
The pad gel is dried out
The pads are discolored
The pad wires are damaged

PRECAUTION: Occasional gel peel may occur. If gel peel exposes silver area of the pads, discard the pads.

PRECAUTION: Pads packaging should only be opened immediately prior to use.

PRECAUTION: Pads are not reusable and not sterile.

PRECAUTION: Pads should be stored in a cool and dry place.

PRECAUTION: During defibrillation, air pockets between the skin and pads may cause skin burns. Apply pads so that the entire pad adheres to skin. Do not reposition the pads once applied. If pad position must be changed, remove and replace with new pads.

PRECAUTION: Prolonged non-invasive pacing may cause skin irritation and burns, especially with higher pacing current levels. Discontinue non-invasive pacing if skin becomes burned and another method of pacing is available. Discontinue use of pads if allergic or adverse skin reaction occurs.

PRECAUTIONS (CONTINUED)

PRECAUTION: Pads that are dried out or damaged may cause electrical arcing and patient skin burns during defibrillation. Do not use pads beyond the expiration date.

PRECAUTION: The maximum duration of pacing is recommended at one (1) hour. If patient condition requires prolonged continuous pacing it is recommended that pads should be replaced to ensure maximum patient benefit. Prolonged pacing particularly in neonates or adults with severely restricted blood flow, may cause burns. Periodic inspection of the underlying skin is recommended.

PRECAUTION: Check that pad adhesive is intact and undamaged.

PRECAUTION: Do not discharge using standard paddles on top of pads.

PRECAUTION: Do not use isopropyl alcohol on the Responder 2000 pads.

PRECAUTION: Use only the specified electrodes in Section 7 of this manual with the Responder 2000. Some electrodes maybe subject to large offset potentials due to polarization. Recovery time after application of defibrillator pulses may be especially compromised. Squeeze bulb electrodes may be particularly vulnerable to this effect.

PRECAUTION: Printer paper may jam if paper is wet. Printer may be damaged if wet paper is allowed to dry while in contact with printer elements.

PRECAUTION: Select the energy level appropriate for the patient's age. The Responder 2000 does not select the energy or shock sequences based on the defibrillation pads connection.

PRECAUTION: Check that pad adhesive is intact and undamaged.

PRECAUTION: To prevent damage to equipment, do not clean any part of the Responder 2000 or its accessories with phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not steam, autoclave, or gas-sterilize the Responder 2000 or accessories.

PRECAUTION: Environment of use
Responder 2000 is designed for indoor use. Operator must confirm that the environment of use meets the required operating environmental specifications before using.

PRECAUTION: Cold Environments
If the Responder 2000 is stored in an environment with a temperature below the operating temperature, the unit should be allowed to warm up to the needed operating temperature before using.

PRECAUTION: Federal law restricts this device to be sold by or on the order of a physician or practitioner licensed by state law in which he/she practices to use or order the use of the device.

PRECAUTION: Line isolation monitor transients may resemble actual cardiac waveforms, and thus inhibit heart rate alarms. To minimize any possible interference, apply electrodes correctly as indicated in this manual. Arrange lead wires away from the line isolation monitors and power cords, and use independent means to verify the correct heart rate is being displayed.

PRECAUTION: Possible electrical interference with device performance
Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI), which could affect the performance of this device. RFI may result in distorted ECG and failure to detect a shockable rhythm. Avoid operating the Responder 2000 near cauterizers, diathermy equipment, FM 2-way radios, or cellular phones. Turn power off to radio, cellular and other like equipment near the Responder 2000. Refer to the EMI tables in section 6.

PRECAUTION: Possible Interference with Implanted Pacemaker
Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The Responder 2000 has pacemaker detection and rejection; however with some pacemakers the Responder 2000 may erroneously count pacemaker spikes and not advise a defibrillation shock. If possible, it is recommended that the Responder 2000 be used in Manual Mode for patients with implanted pacemakers.

PRECAUTIONS (CONTINUED)

PRECAUTION: Moving the Patient while Responder 2000 is attached
During a rescue attempt, excessive jostling or moving of the patient may cause the Responder 2000 to improperly analyze the patient's cardiac rhythm. Stop all motion or vibration before attempting to use the Responder 2000.

PRECAUTION: Systems Statement
Equipment connected to the Responder 2000 must be certified to the respective IEC Standards (i.e. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Anybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible that the system complies with the requirements of the system standard IEC 60601-1-1. The Responder 2000 Service Port is only intended for use during maintenance by authorized service personnel.

PRECAUTION: Monitors, defibrillators, and their accessories (including pads and cables) contain ferromagnetic materials and must not be used in the presence of the high magnetic field created by a Magnetic Resonance Imaging (MRI) device. The high magnetic field created by an MRI device will interact with ferromagnetic equipment that may cause serious injury to persons between the equipment and the MRI device. Skin burns will also occur due to heating of electrically conductive materials, such as patient leads and pulse oximeter sensors. Consult the MRI manufacturer for more information on interaction with ferromagnetic materials and equipment.

PRECAUTION: Observe the ECG rhythm. Confirm that the full length sync bar appears near the middle of each QRS complex. If the sync bars do not appear or are displayed in the wrong locations change the lead source.

NOTES

NOTE: Responder 2000, pads, and electrodes are latex-free.

NOTE: Keep valid certificates of training and certification as required by state, province, or country regulations.

NOTE: If the Battery Charger Charge Status light blinks red, a battery error has occurred during charging. If the Charge Status light is solid red, a charger error has occurred during charging. Contact Customer Service in the event of an error during charging.

NOTE: If the Responder 2000 indicates an error code when powering on the device:
Do not use the Responder 2000 (Remove from patient)
Contact Customer Service with the error code(s).

NOTE: If the system is pacing when the power button is pressed, a confirmation box displays requiring an additional press of the Rotary Selector Knob before the system will turn off.

NOTE: If the power button is pressed for five (5) seconds, the Responder 2000 will power down.

NOTE: If AC power is not connected and the battery voltage becomes critically low, the system will display an error message and then will power off.

NOTE: If the ECG cable becomes disconnected or falls off, a warning message is displayed.

NOTE: As the battery ages, it will discharge faster and there will be less operating time available before low battery warning, therapy inhibit and system shutdown. Replace an aged battery to restore the operating time.

NOTE: If the Responder 2000 issues an Error during this process:
Do not use the Responder 2000 (Remove from patient)
Write down any displayed error codes and contact Customer Service

NOTE: Anterior / Posterior pads placement may alleviate a PADS SHORTED message.

NOTE: The skin is a poor conductor of electricity, therefore preparation of the patient's skin is important to facilitate good electrode to skin contact. When cleaning the patient's skin, NEVER use alcohol or tincture of benzoin, as this increases skin resistance.

NOTE: The selectable energy when using internal paddles is as follows: 2, 3, 5, 7, 10, 15, 20, 30, and 50 Joules.

NOTE: Alarm Silence symbol is displayed, indicating that no audible tone warnings will be heard; only written warning messages will be displayed on the graphics display.

NOTE: The operator has thirty (30) seconds to deliver therapy before the Responder 2000 disarms and aborts therapy.

NOTE: In Auto Sequence if the user wants to deliver a Sync Shock, Sync should be selected individually for all shocks in Auto Sequence.

NOTE: Every time after a Sync Shock is delivered; the device resets this toggle button to "No Sync".

NOTE: Verify printer has adequate paper on its roll for use.

NOTE: To change the password, see TO CHANGE THE PASSWORD in this section of the manual.

NOTE: All changes to the settings of the Responder 2000 must be performed before connecting the Responder 2000 to the patient.

NOTE: Changes to the power-up default in Menu, do not change on display.

NOTE: The warranty will be void upon unauthorized disassembly or service of the Responder 2000.

SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the Responder 2000, or on its accessories. Some of the symbols represent standards and compliances associated with the Responder 2000 and its use.

Consult instructions for use of the Responder 2000 and/or its accessories.

Precaution: Consult accompanying documents

Authorized Representative in the European Community

CE Marked per the Medical Device Directive 93/42/EEC of the European Union. The notified body is BSI (ID# 0086).

CE Mark: The Responder 2000 battery charger conforms to essential requirements of Directive EMC 83/336/EEC.

Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, IEC 60601-1 and IEC 60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.

Dangerous Voltage: The defibrillator output has high voltage and can present a shock hazard. Please read and understand all safety alerts in this manual before attempting to operate the Responder 2000.

Month and Year of manufacture.

xx/xxxx

Defibrillation-proof Type BF Applied Part = The SpO2 sensor/cable is isolated and can withstand the effects of an externally applied defibrillation shock to the patient.

Defibrillation-proof Type CF Applied Part = The ECG, Pads, Paddles, and Spoon are isolated, can withstand the effects of an externally applied defibrillation shock to the patient, and are specifically designed for applications where a conductive connection directly to the heart is established.

Device Model Number. Battery Model Number.

For use by or on the order of a Physician, or persons licensed by state law.

Lot Number

Manufacturer

Points to important information regarding the use of the Responder 2000.

Power button: When pressed, turns the Responder 2000 on and off. This symbol also indicates when the Responder 2000 has power.

IP22

The enclosure of the Responder 2000 is protected against the ingress of dripping water in accordance with EN 60529. The enclosure of the Responder 2000 is protected against ingress of solid foreign objects greater or equal to 12.5 mm in accordance with EN 60529. The enclosure of the Responder 2000 also provides protection for user fingers against access to hazardous parts in accordance with EN 60529.

The Z-bar provides a relative visual indicator of the total transthoracic impedance between the two defibrillation pads.

This symbol indicates protective earth (ground).

This symbol indicates the equipment is suitable for alternating current.

SN

Specifies serial number of the Responder 2000

Do not burn or incinerate rechargeable battery.

Rechargeable battery

Recycle or dispose of the lithium-ion battery in accordance with all federal, state and local laws.

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Lithium Ion

This symbol indicates the Responder 2000 battery is charging.

This symbol indicates that Responder 2000 requires service. Please take the Responder 2000 out of service and contact Customer Service.

1 Symbol on Responder 2000 front panel control indicates Power on/off

2 Symbol on Responder 2000 front panel and Apex paddle control indicates Charge

3 Symbol on Responder 2000 front panel and Apex and Sternum paddles indicates Shock

Manual Symbol on Responder 2000 front panel indicates Manual Mode. This blue button can turn manual mode on or off.

SAFETY AND PERFORMANCE STANDARDS

The Responder 2000 has been designed and manufactured to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). The Responder 2000 conforms to the applicable requirements of the following:

CE 0086

CE marked by BSI 0086 per the Medical Device Directive 93/42/EEC of European Union

ETLClassified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, IEC 60601-1 and IEC 60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.

Electrical, Construction, Safety and Performance
IEC 60601-1 (1988), Amendments 1 (1991) & 2 (1995)
IEC 60601-2-4 (2002)
ANSI/AAMI DF-80 (2003)

Electromagnetic Compatibility (EMC)
IEC 60601-1-2 (2001)
IEC 60601-2-4 (2002) Section 36
ANSI/AAMI DF-80(2003) Section 36

The Responder 2000 needs to be installed and put into service according to the EMC information specified in this manual.

Refer to Section 6 of this manual for a complete list of all Safety Standards.

OPERATOR TRAINING REQUIREMENTS

Persons authorized to operate the Responder 2000 must have all of the following minimum training.

- Defibrillation training and other training as required by state, province, or country regulations.
- Training on operation and use of the Responder 2000.
- Training in manual defibrillation
- Additional training as required by the physician or Medical Director.
- A thorough understanding of the procedures in this manual.

NOTE: Keep valid certificates of training and certification as required by state, province, or country regulations.

WARNING: The Responder 2000 is not intended to be deployed in settings or situations that promote use by untrained personnel. Operation by untrained personnel can result in injury or death.

SECTION 2: GETTING STARTED

OVERVIEW

This section presents information on unpacking and setting up the Responder 2000

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SETTING UP THE RESPONDER 2000	25
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USING THE BATTERY CHARGER	27
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UNPACKING AND INSPECTING

Every attempt is made to ensure your order is accurate and complete. However, to be sure that your order is correct, verify the contents of the box against your packing slip.

The Responder 2000 is designed for simplicity of operation and set-up and requires minimal assembly. The following items are included in the Responder 2000 box:

One (1) Responder 2000

One (1) Set of external paddles

One (1) Rechargeable battery

One (1) Operator's manual

One (1) Power cord

One (1) Roll of Printer paper

Carefully inspect each item as it is unpacked for any signs of damage which may have occurred during shipment.

- Check the components according to the packing list.
- Check for any damage or defects. Do not attempt to setup the Responder 2000 if anything is damaged or defective. Contact Customer Service immediately if anything is damaged or defective.

SETTING UP THE RESPONDER 2000

This section provides the basic set up information you need to prepare the Responder 2000 for operation and to connect the optional monitoring accessories.

RECHARGEABLE BATTERY INSTALLATION AND REMOVAL

The Responder 2000 uses a rechargeable battery. The rechargeable battery is not shipped fully charged and it is recommended that you charge the battery fully before using. With a new battery at room temperature, the Responder 2000 will first indicate "Low Battery" while there is still sufficient charge remaining to perform at least five (5) rescues. As the battery ages, there will be progressively less operating time available before low battery warning, after low battery warning before therapy inhibit, and after therapy inhibit before system shutdown. Operation at other than room temperature, especially at low temperature, will also reduce battery capacity. It is recommended to recharge the battery as soon as practical after the "Low Battery" indication. Always have immediate access to a fully charged, properly maintained battery. Replace the battery or connect the Responder 2000 to AC power when the device displays a low battery warning. The remaining capacity of the battery can be estimated by pressing the test button on the battery.

PRECAUTION: Storage of batteries at elevated temperatures will significantly reduce capacity. It is recommended that batteries be stored and recharged only at room temperature, about 21°C. In any case, do not exceed 50°C.

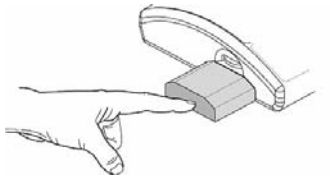
NOTE: As the battery ages, it will discharge faster and there will be less operating time available before low battery warning, therapy inhibit and system shutdown. Replace an aged battery to restore the operating time.

NOTE: When storing batteries for extended periods of time, store at 25-50% state of charge for best battery life.

NOTE: Battery state of charge will decline during storage. Be sure to charge the battery fully before using and after storage.

TO INSTALL THE RECHARGEABLE BATTERY

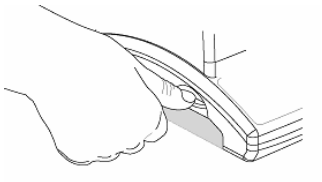
1. Place the Responder 2000 onto a secure, level surface.
2. With the label uppermost and the connector facing inward, insert the battery in the slot on the left side of the Responder 2000 as shown.



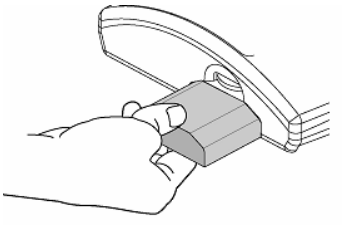
3. Push the battery in until the battery securing latch clicks into place.

TO REMOVE THE BATTERY

1. Press the battery release until the battery ejects.



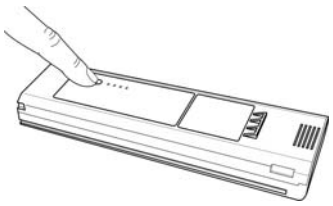
2. Pull the battery straight out until it clears the housing.



WARNING: The Responder 2000 should not be stored with the battery inserted. Remove the battery from the Responder 2000 when storing the device.

TO CHECK THE BATTERY

1. Press the test button on the top of the battery.



2. The row of lights will all light up when the battery is fully charged.

3. If the lights do not light up, or only partially light up, the battery is fully or partially discharged.

USING THE BATTERY CHARGER

With a new battery at room temperature, the Responder 2000 will first indicate “Low Battery” while there is still sufficient charge remaining to perform at least five (5) rescues. As the battery ages, there will be progressively less operating time available before low battery warning, after low battery warning before therapy inhibit, and after therapy inhibit before system shutdown. Operation at other than room temperature, especially at low temperature, will also reduce battery capacity. It is recommended to recharge the battery as soon as practical after the “Low Battery” indication.

Figure 2.1 Battery Charger and Power Supply

1. Remove the rechargeable battery from the Responder 2000.

2. Plug the power cord into the power supply, plug the power supply into the battery charger, and plug the power cord into an AC outlet.

3. Insert the battery into the charger and ensure the following:

   - Operating *Mode* light is solid green
   - Charge *Status* light is flashing green.

4. Battery charging starts automatically when battery is put in the battery charger.
   Do not push the *Calibrate* button unless a calibration cycle is desired.

5. The battery will take up to 4 (four) hours to charge in the charger.

6. Remove the battery from the charger when it is charged. The battery is fully charged, when the *Mode* light is solid green and the *Status* light is off.

7. Charging may be terminated early by removing the battery from the charger.

NOTE: If the Charge *Status* light blinks red, a battery error has occurred during charging. If the Charge *Status* light is solid red, a charger error has occurred during charging. Contact Customer Service in the event of an error during charging.

THE BATTERY CALIBRATION CYLE

Time, repeated partial charges and discharges, and battery aging will lead to inaccuracy of the battery fuel gauge. This is corrected by performing a battery calibration cycle. To initiate a calibration cycle, press the *Calibrate* button after the battery has been inserted into the charger. The *Mode* light will turn red indicating a calibration cycle is in progress. The calibration cycle consists of a full charge, full discharge, and full charge of the battery. The cycle may take up to 20 hours to complete. If it is desired to abort the calibration cycle, press the *Calibrate* button again. When a calibration cycle is aborted, the *Mode* light will turn green and the charger will charge the battery. When the calibration cycle is complete, the *Mode* light will turn green.

CALIBRATING BATTERY WHILE INSIDE THE RESPONDER 2000

To calibrate a battery while inside the Responder 2000, perform a full cycle of charge, discharge, and charge.

Perform a full cycle of charge for at least 8 hours (see below).
Disconnect the Responder 2000 from AC power. Turn the Responder 2000 on and wait until the device shuts down.
Perform a full cycle of charge for at least 8 hours (see below). When the battery is fully charged, the battery indicator will display “full battery” (see also section ON-SCREEN INDICATORS).

CHARGING BATTERY WHILE INSIDE THE RESPONDER 2000

Connect the supplied power cord to the socket at the rear of the Responder 2000 then plug in to a suitable AC power source. The battery will automatically charge when the power cord is connected to the Responder 2000. The battery will take up to eight hours to charge in the Responder 2000.

WARNING: A protective ground connection by way of the grounding conductor in the power cord is essential for safe operation. To avoid electrical shock, plug the power cord into a properly wired receptacle, use only the power cord supplied with the device, and make sure the power cord is in good condition.

WARNING: If the integrity of the external power earth conductor arrangement is in doubt, unplug the device from the mains AC and operate it from a Responder 2000 rechargeable battery that is charged.

WARNING: If battery is missing or low, the Responder 2000 will not power on if AC power is lost.

CONNECTING PADDLES OR PADS

The defibrillator paddle connector attaches to the rear of the Responder 2000. The connector for defibrillator paddles and pads attaches at the same location. With the label facing out, align the connector over the port and press firmly into place.

STORING THE PADDLES

The paddles dock easily on each side of the Responder 2000. Simply push and click to secure as shown in Figure 2.2 below. The paddles can be docked with the cables pointing up or down as preferred.

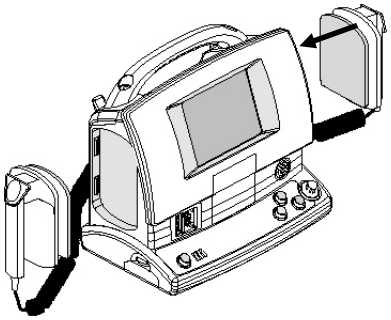


Figure 2.2 Docking the Paddles

CONNECTING THE ECG LEADS

The Responder 2000 accepts either 3-lead or 5-lead ECG cables. Align the ECG connector with the green port in front Responder 2000. Push the ECG cable firmly into the ECG port.

Once the ECG connector is attached, a 3-lead or 5-lead wire can be connected to the other end of the cable as shown in Figure 2.3 below.

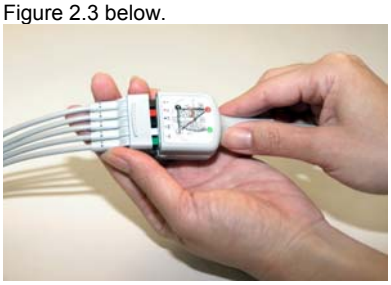


Figure 2.3 Attaching the ECG connector to a 5-lead wire

CONNECTING THE SPO_2 CABLE (OPTIONAL FEATURE)

The Responder 2000 has SpO_2 as an option on certain models. Align the SpO_2 connector with the blue port in front Responder 2000. Push the SpO_2 cable firmly into the SpO_2 port as shown in Figure 2.4 below.

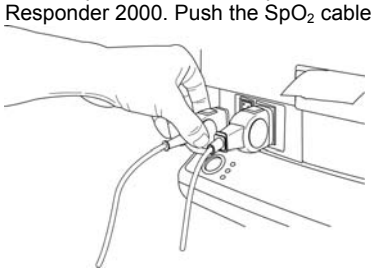


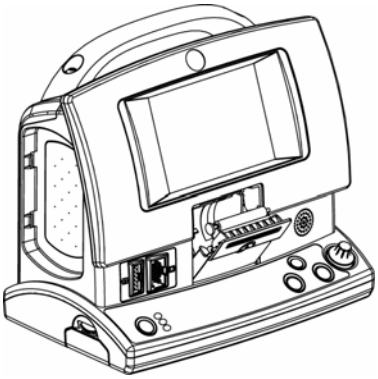
Figure 2.4 Attaching the Oximetry Sensor Lead

INSTALLING PAPER INTO THE PRINTER

To install paper into the printer, follow these instructions.

Lift up on the front printer flap as shown by arrow on the Responder 2000. Pull door flap up and forward to open the printer.

Place paper roll into the printer with the paper end pulled over the top of the printer roller through the opening in the printer door. Refer to printer door for proper direction of paper.



Close the printer and press the door into place until it clicks. The paper should be protruding from the slot in the printer housing. The paper may be torn off flush with the front of the Responder 2000 after installation.

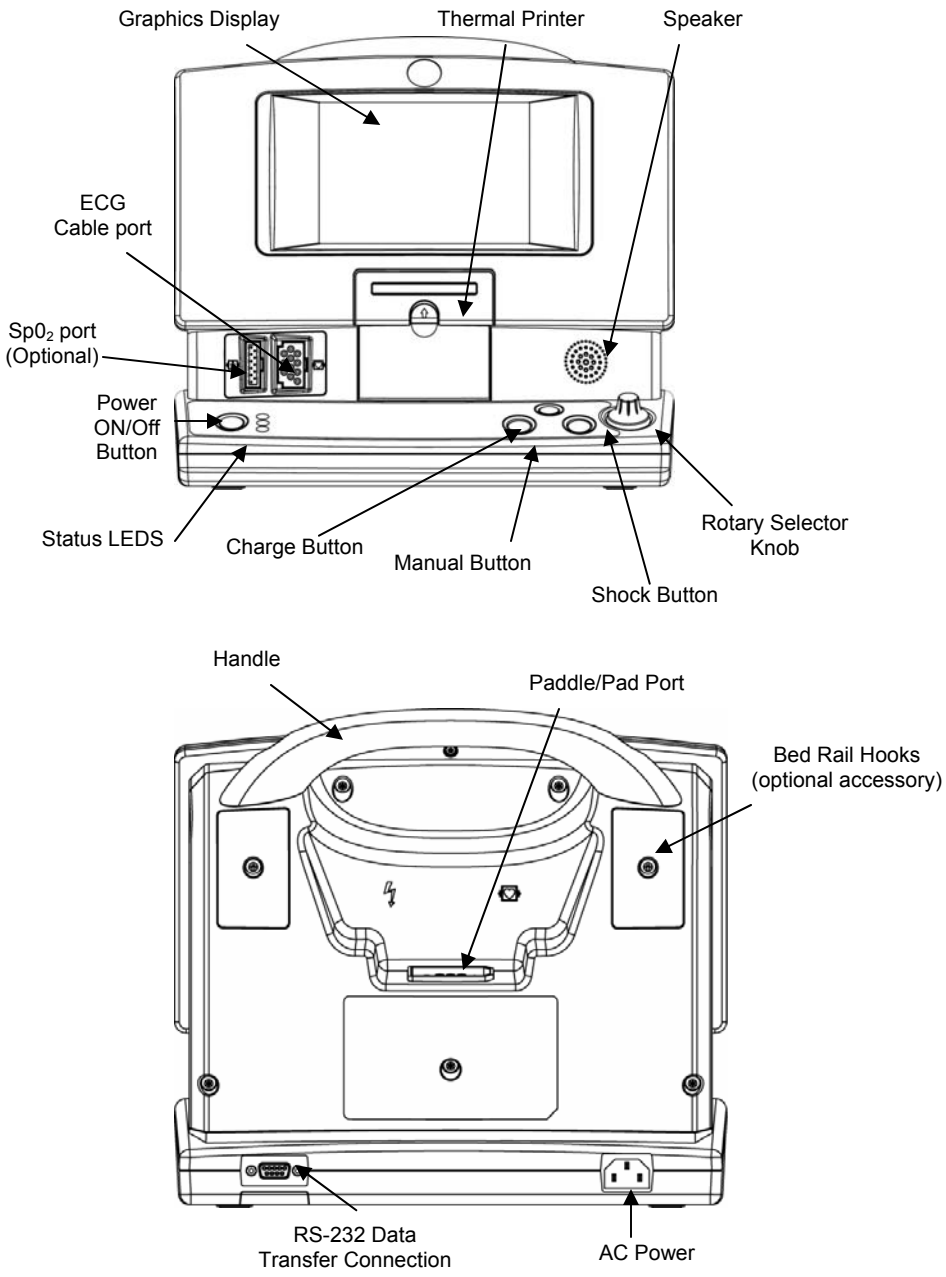
PRECAUTION: Printer paper may jam if paper is wet. Printer may be damaged if wet paper is allowed to dry while in contact with printer elements. Use only printer paper listed in section 7 “Accessories”.

POWERING THE RESPONDER 2000

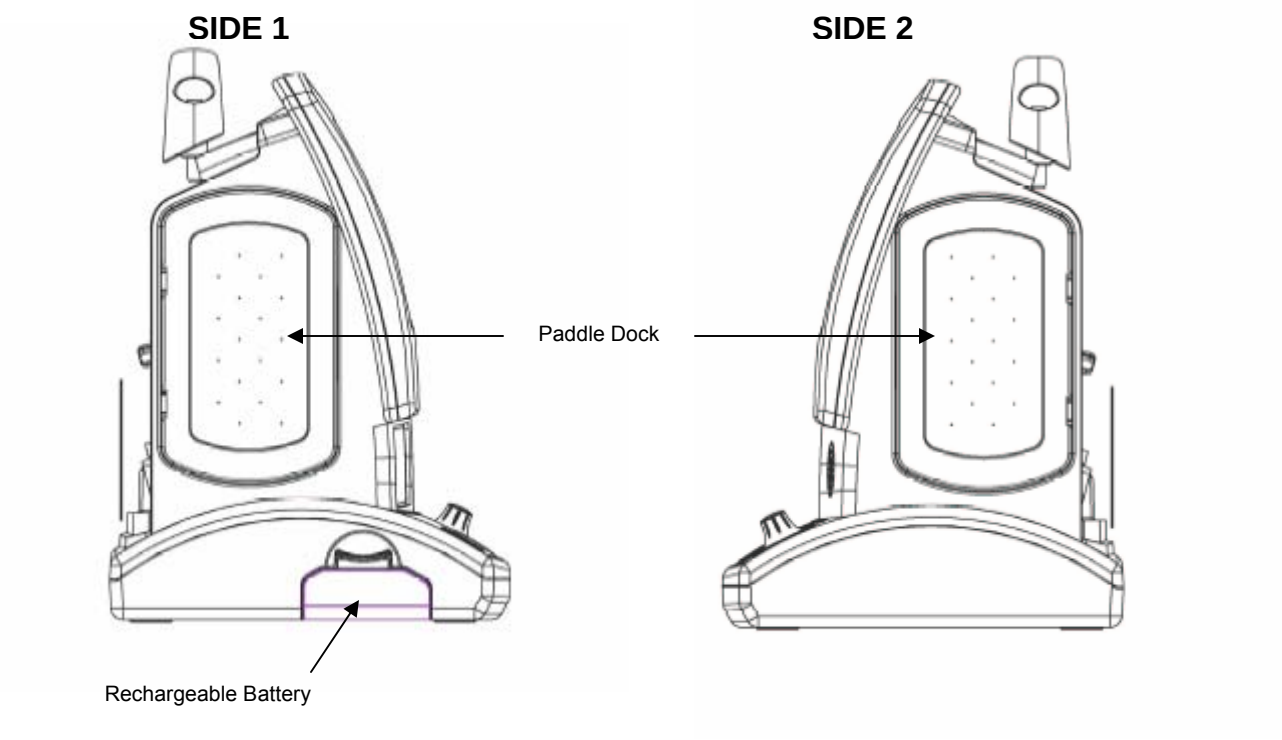
The Responder 2000 operates safely from the following power sources:

- Rechargeable battery
- AC power using the supplied power cord

RESPONDER 2000 FRONT AND BACK CONTROLS AND INDICATORS



RESPONDER 2000 SIDE CONTROLS AND INDICATORS



Z-BAR™ INDICATOR

The Z-Bar provides a relative visual graphical indicator of the total transthoracic impedance between the two defibrillation pads or paddles. The Z-Bar is used in the assessment of:

- Adequate Pad, Paddle , or Spoon placement
- Pad or Paddle quality and integrity
- Pad or Paddle adhesion to the patient's skin
- Pad or Paddle connection to the Responder 2000
- Provides for quick assessment between OFF and SHORTED

Z-BAR FOR PADS AND PADDLES

SECTION	MEASURED IMPEDANCE RANGE (OHMS)	DESCRIPTION	COLOR FILL
1	0-24Ω	Lower Limit – Non-operational range	Red
2	25-35Ω	Lower marginal operating range. Indicates potential degradation in quality or position	Yellow
3	36-135Ω	Normal operating range	Green
4	136-200Ω (for pads) >136Ω (for paddles)	Upper marginal operating range. Indicates potential degradation in quality or position	Yellow
5	>201Ω (for pads)	Upper Limit– Non-operational range	Red

Z-BAR FOR SPOONS

SECTION	MEASURED IMPEDANCE RANGE (OHMS)	DESCRIPTION	COLOR FILL
1	0-9Ω	Lower Limit – Non-operational range	Red
2	10-15Ω	Lower marginal operating range. Indicates potential degradation in quality or position	Yellow
3	16-75Ω	Normal operating range	Green
4	76-200	Upper marginal operating range. Indicates potential degradation in quality or position	Yellow
5	>201Ω	Upper Limit– Non-operational range	Red

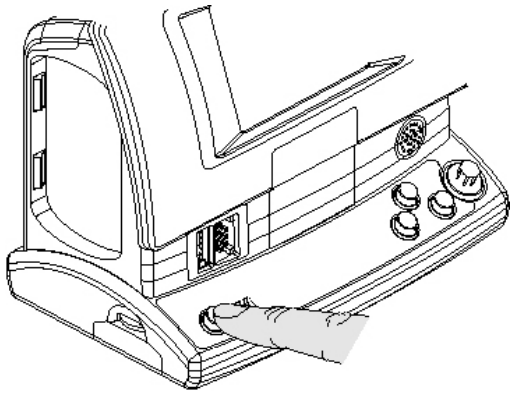
BUTTONS

There are 4 buttons on the Responder 2000:

1. Power Button
2. Charge Button
3. Shock button
4. Manual Button

POWER BUTTON

To Power on and off the Responder 2000, push the green Power button on the front panel of the Responder 2000.



POWER ON

1. Press the green power button to turn on the Responder 2000. As the Responder 2000 powers on, the system performs a self-test.
2. After the Responder 2000 is powered on, it will automatically go into Manual Mode. The user can also program it to enter Semi-Auto Mode or Monitor mode upon power on of the device.

NOTE: If the Responder 2000 indicates an error code when powering on the device:

- Do not use the Responder 2000 (Remove from patient)
- Contact Customer Service with the error code(s).

POWER OFF

Press the green power button to turn off the Responder 2000.

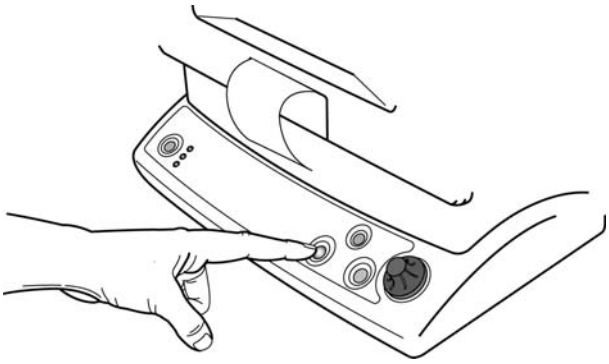
NOTE: If the system is pacing when the power button is pressed, a confirmation box displays requiring an additional press of the Rotary Selector Knob before the system will turn off.

NOTE: If the button is pressed for five (5) seconds, the Responder 2000 will power down.

NOTE: If AC power is not connected and the battery voltage becomes critically low, the system will display an error message and then will power off.

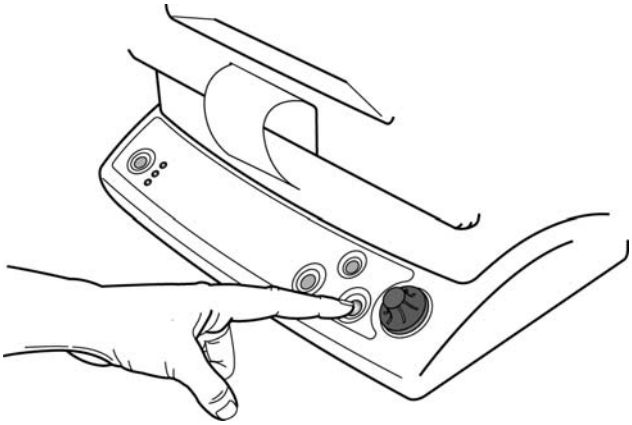
CHARGE BUTTON

The charge button is used to manually charge the Responder 2000 to the selected energy level. This button is only used in Manual Mode. This button is disabled when paddles are connected to the Responder 2000. In this case, the Responder 2000 will be charged only from the paddle charge button. The button will also be disabled when the Z-Bar is in the red range for pads or spoons.



SHOCK BUTTON

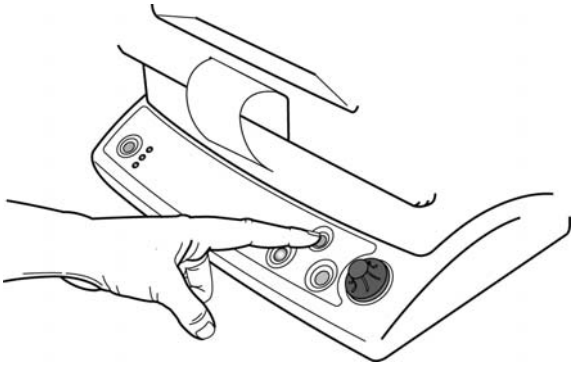
The shock button activates (flashes red) only when the system is charged and ready to deliver therapy to the patient. Press and hold the shock button until therapy is delivered. This button is disabled when the paddles are connected to the Responder 2000. If pads or spoons are used, the shock button will only be activated with good impedance.



MANUAL BUTTON

The manual buttons brings the operator in or out of the Manual Mode Screen, which allows the operator to begin or end a shock sequence. If the manual button is pushed during Pacing, the operator needs to confirm entry of Manual Mode before Manual Mode is entered.

Press the Manual button to enter or exit manual defibrillation mode.



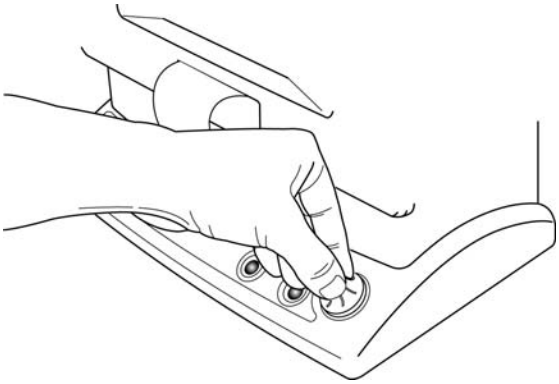
ROTARY SELECTOR KNOB

The Rotary Selector Knob is used for scrolling through (a) all areas of the monitoring screen (set-up menus, sub-menus) (b) selecting soft keys and (c) setting values. This knob is the primary operator navigation and selection vehicle for the Responder 2000. It can rotate clockwise and counterclockwise. To make a selection, press the Rotary Selector Knob. The knob is always active while the system application is running.

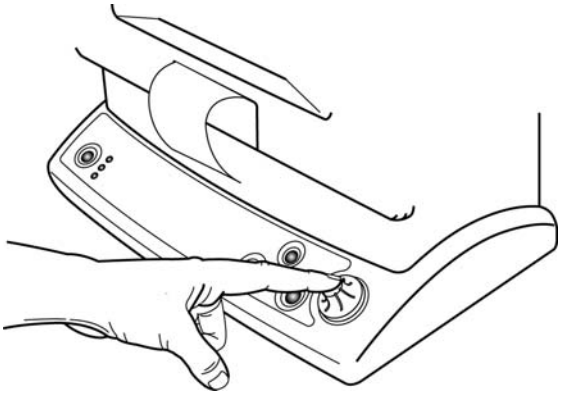
SOFT KEYS

Soft keys are buttons which are displayed on the graphics display and are activated by using the Rotary Selector Knob.

1. **HIGHLIGHT** the selection by rotating the Rotary Selector Knob to move the highlight around the screen until the setting you wish to change is highlighted.



2. **SELECT** the item by pressing the Rotary Selector Knob until it clicks.



STATUS LEDS

There are three system status LEDs on the front panel of the Responder 2000

	AC Power (Green LED)	The AC Power LED is lit when the Responder 2000 is connected to external AC power.
	Battery Charging (Yellow LED)	The Battery Charging LED is lit when the Responder 2000 Battery is charging in the Responder 2000 or the battery charge is being maintained.
	Service Required (Red LED)	The Service Required LED is lit when the Responder 2000 requires service. Please take the Responder 2000 out of service and Contact Customer Service.

PADDLE CONTROLS

The Apex paddle has one button, which controls both charge and shock. Press the Apex paddle button to charge the Responder 2000. After the Responder 2000 is charged, press both the Apex and Sternum paddle buttons simultaneously to deliver the shock. Charge and Shock are only activated when the system is in the proper defibrillation mode. If a button is stuck or remains pressed from before activation of defibrillation, it must be released before a further press is accepted. When the paddles are connected to the Responder 2000, the charge and shock buttons on the front panel will be disabled. The charge button is enabled only when the Responder 2000 is in Manual Mode.

RS-232 DATA TRANSFER CONNECTION

This feature is used by factory authorized personnel only.

GRAPHICS DISPLAY

MONITOR SCREEN

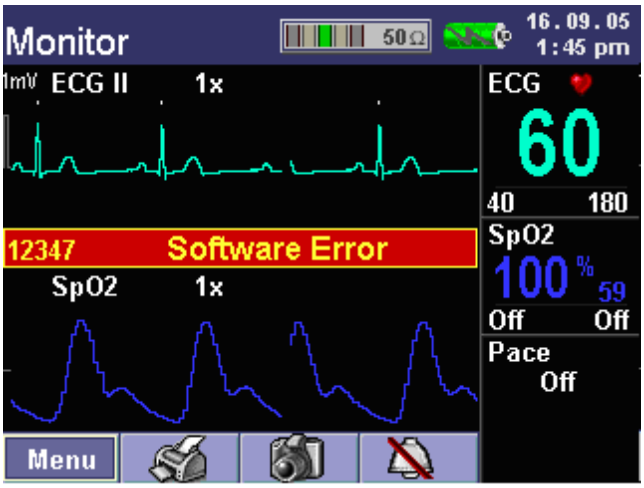
The monitor screen contains the information bar, Channel 1 and 2 waveforms, information areas for ECG, Pacing and SpO_2 areas.

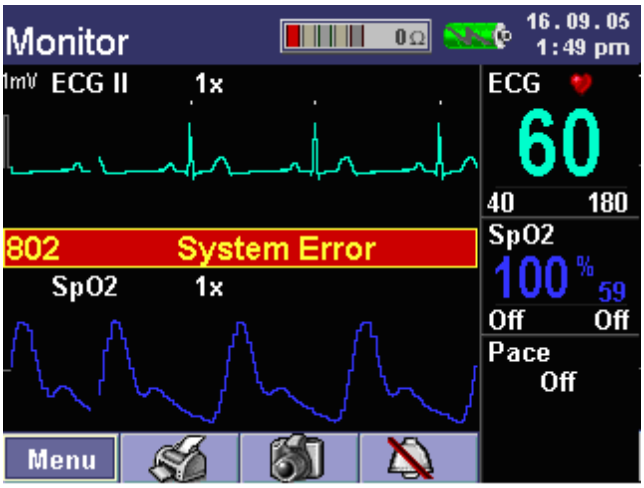
INFORMATION BAR

At the top of the screen is the Information bar showing the operating mode of the Responder 2000, the impedance display, a battery charge status indicator and the current date and time.

MESSAGE AREA

In the middle of the screen, the Responder 2000 displays messages for software and system errors.





CHANNEL 1

If 3-lead or 5-lead ECG cables are connected to the Responder 2000, the ECG monitoring waveform is displayed in Channel 1. The same waveform can be cascaded (continued) from Channel 1 to Channel 2 if desired. Typically, the system will display the power-on default of **ECG II** until a different lead combination is chosen.

Each channel has an input source (the ECG lead number) and Gain information associated with its trace waveform. To change these settings, simply rotate the Rotary Selector Knob to highlight the field and press the Rotary Selector Knob to select it. Rotate to cycle through the field value options and press the Rotary Selector Knob again to confirm the new setting.

The system will display waveforms in channel 1 based on the following conditions:

- If just an ECG cable is connected, the input sources available for the operator to select on channel 1 are:
    - When an ECG cable is connected: I, II, III, aVR, aVL, aVF, V, Paddles (with Paddles off message)

NOTE: If the ECG cable becomes disconnected or falls off, a warning message is displayed.

- If ECG is not connected, but Pads, Paddles, or Spoons are, the channel will automatically convert to the connected input if the Auto-Switch source is turned on.
- If Pads, Paddles, or spoons are connected along with the 5-lead ECG cable, the following source input options are available:
    - I, II, III, aVR, aVL, aVF, V, Pads, Paddles, Spoons
    - If the ECG cable or the Pads, Paddles, or Spoons become disconnected or fall off, a warning message is displayed.
    - If no ECG or Pads are connected, it will indicate that no leads are connected by showing dashed line.

CHANNEL 2

Displays one of the following selectable choices:

- Cascaded waveform from Channel 1
- The SpO_2 waveform (if sensor is connected and Responder 2000 has this optional feature.)

INFORMATION AREAS

The right side of the screen contains specific monitoring information for ECG (top box), SpO_2 (Oximetry) and Pacing if these two options are present. To access the information areas:

1. Rotate the Rotary Selector Knob until the outline of the information box is highlighted then press to select the information area.
2. Rotate the Rotary Selector Knob again to highlight a particular item within the highlighted box to change the setting. Press to select the item then turn the knob to scroll through the value range for that item.
3. Press to confirm a new value.

ECG INFORMATION BOX

The ECG Information box shows ECG information.

The value shown for heart rate is determined from the ECG of channel 1 input, which can be from ECG electrodes or Pads, paddles or spoons.

The low and high alarm ECG limits can also be set from this box.

SPO_2 INFORMATION (OPTIONAL)

When the pulse oximetry option is present and a sensor is connected, the SpO_2 Information area displays SpO_2 information. The SpO_2 information area displays % saturation and pulse rate. SpO_2 high and low alarm limits can be changed from the SpO_2 information box.

PACING INFORMATION (OPTIONAL)

When the Pacing option is present and pads are connected, pacing can be turned on. Pacing mode, rate, and pace current can be set within this information box.

ON-SCREEN INDICATORS

BATTERY INDICATOR

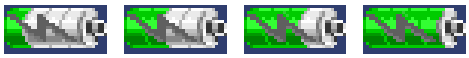
The battery indicator graphically displays the approximate percentage of battery life remaining.

Four (4) ranges will be shown:

~0-25% ~25-50% ~50-75% ~75%-100

When AC is not present and the display falls to a single bar, the bar turns red to indicate that the battery should be charged soon, or that a fully charged battery should be inserted.

When the Responder 2000 is connected to AC, a "lightning bolt" indicates that the battery is being charged or charge is being maintained if the battery is full. When AC is not present, no lightning bolt is displayed.



When no battery is present, the following indicator is displayed.

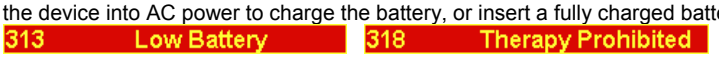
BATTERY WARNING MESSAGES

When running the Responder 2000 from the rechargeable battery, a low battery may cause the following warning messages:

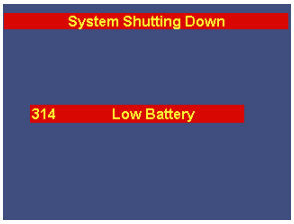
1. Message 312
   When battery voltage is low, Message 312 is displayed. Plug the device into AC to charge the battery, or insert a fully charged battery.

2. Message 313 and Message 318

   When battery voltage is very low, the Message 313 and Message 318 alternate, and therapy is inhibited. Plug the device into AC power to charge the battery, or insert a fully charged battery.

3. Message 314
   When battery voltage is critically low, Message 314 is displayed momentarily and the system shuts down. Plug the device into AC to charge the battery, or insert a fully charged battery. Turn the device back on if in use.

NOTE: As the battery ages, it will discharge faster and there will be less operating time available before low battery warning, therapy inhibit and system shutdown. Replace an aged battery to restore the operating time.

HEART RATE

The red heart symbol displayed in the ECG information area will graphically indicate the heart rate by beating at the rhythm of the patient's heart rate. For clear viewing, the heart will display upon detection of an R-Wave for 200ms. The Responder 2000 uses the average of the time between the last eight (8) detected QRS complexes, with the two outlying values discarded, to calculate the displayed heart rate. The heart rate display is updated once every 2 seconds.

The Responder 2000 will respond to a change in heart rate from eighty (80) bpm to one hundred and twenty (120) bpm in less than five (5) seconds. The Responder 2000 will respond to a change in heart rate from eighty (80) bpm to forty (40) bpm in less than ten (10) seconds in the conditions specified in ANSI/AAMI EC13 section 4.1.2.1 f).

WARNING: Do not rely solely on heart rate readings; assess the patient at all times.

SECTION 3: USING THE RESPONDER 2000

OVERVIEW

This section describes how to prepare the Responder 2000 and the patient and using the Responder 2000.

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RESPONDER 2000 PREPARATION

1. Setup Responder 2000 according to directions in Section 2.

2. Verify Responder 2000 Indications for Use are being met. Refer to Section 1.

3. Verify Responder 2000 Safety Terms and Conditions are being met. Refer to Section 1.

Prepare the patient according to directions in the PATIENT PREPARATION in this section.

WARNING: The Responder 2000 is restricted to a single patient at a time.

4. Turn on the Responder 2000 by pushing the Power button on the front panel.

5. The Responder 2000 software will:

   - Perform a Start-up self test
   - Display the Responder 2000 splash screen
   - Illuminate all therapy buttons for a few seconds
   - Output a tone
   - Illuminate the Service LED momentarily

6. When the self-tests are complete, the default operating mode is displayed indicating that the Responder 2000 has successfully passed the start-up self-test and is ready for patient use.

NOTE: If the Responder 2000 issues an Error during this process:
- Do not use the Responder 2000 (Remove from patient)
- Write down any displayed error codes and contact Customer Service

WARNING: Do not use batteries, pads, cables, or optional equipment not specifically approved for the Responder 2000. The use of unapproved equipment may cause the Responder 2000 to function improperly during a rescue.

PATIENT PREPARATION

Follow these recommendations to prepare the patient's skin:

- Remove clothing from the patient's chest.

- If necessary, shave excessive chest hair. Use care not to nick or cut the skin. Avoid placing pads over broken or irritated skin.

- Briskly dry the skin with a towel or gauze to increase capillary blood flow in the tissues, remove skin cells, dirt and excess oil.

USING PADS

The Pads listed in Section 7 of this manual are compatible with the Responder 2000. Adhere to the Precaution and Warnings, Applying PADS, Placement of PADS, Changing of PADS, PADS OFF or SHORTED notifications in this section.

APPLYING PADS

- The pads are not sterile and cannot be sterilized. They are for single patient use and need to be disposed after use.
- Once the pads are applied to the patient they should not be repositioned.
- After placing the pads on the patient, visually check that the pads are firmly attached.
- The skin is a poor conductor of electricity; therefore preparation of the patient's skin is important to facilitate good pads-to-skin contact.
- To ensure proper rhythm analysis by the Responder 2000, patient preparation and hook up must be properly performed. Proper application and placement of the pads are essential for high-quality ECG monitoring. Good contact between the pad and skin minimizes motion artifact and signal interference.

SPECIAL PAD PLACEMENT SITUATIONS

The following descriptions are for special placement situations.

Obese Patients or Patients with Large Breasts
Apply the pads to a flat area of the chest, if possible. If skin folds or breast tissue prevent good adhesion, it may be necessary to spread skin folds apart to create a flat surface.

Thin Patients
Follow the contour of the ribs and spaces when pressing the pad onto the torso. This limits air space or gaps under the Therapy pads and promotes good skin contact.

Patients with Implanted Pacemakers
Place the pads away from the internal pacemaker generator.

ANTERIOR-LATERAL PLACEMENT OF PADS FOR DEFIBRILLATION/SYNC SHOCK (MOST COMMONLY USED)

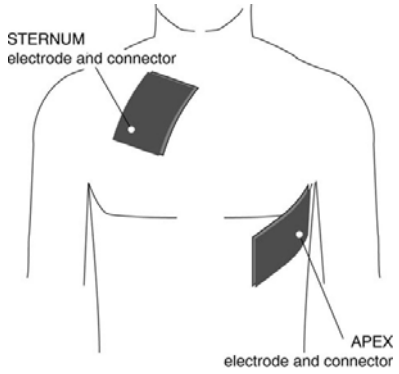
1. Turn off the Responder 2000. Connect the pads connector to the Responder 2000.

2. Shave the application points; this improves conductivity and makes the removal of pads easier.

3. Remove the protective liner by starting with the pad cable connection end. Slowly peel back the protective liner from the pads.

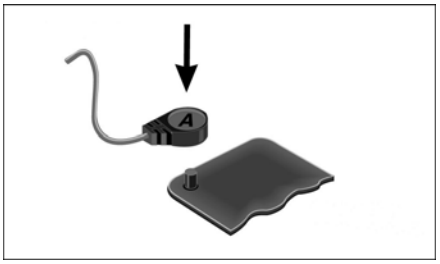
4. Place the anterior (Sternum) pad on the patient's right upper torso, lateral to the sternum and below the clavicle.

5. Place the (Apex) Therapy pad lateral to the patient's left nipple, with the center of the pad in the midaxillary line, if possible. For female patients, position the pad under the breast.



6. Starting from one edge, firmly press the pad onto the patient's chest to eliminate air pockets between the gel surface and the skin.

7. Connect pads cable to the pads.



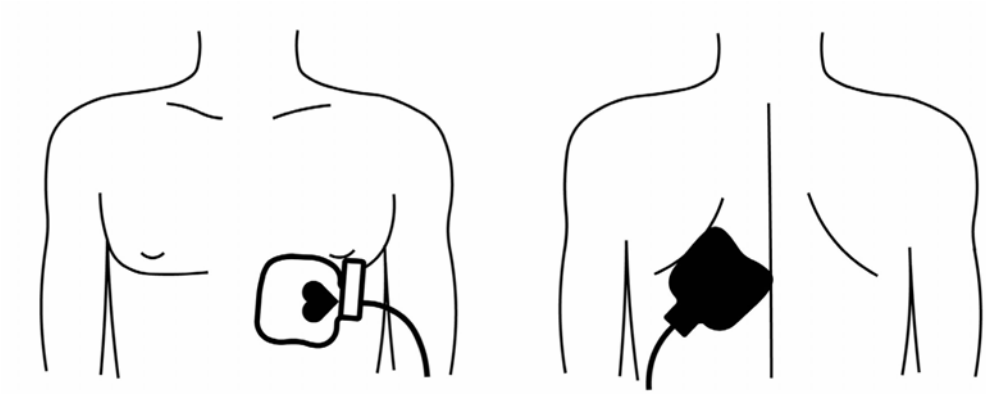
ANTERIOR-POSTERIOR PLACMENT OF PADS FOR NON-INVASIVE PACING AND DEFIBRILLATION/SYNC SHOCK

1. Turn off the Responder 2000. Connect the pads connector to the Responder 2000.

2. Shave the application points; this improves conductivity and makes the removal of pads easier.

3. Remove the protective liner by starting with the pad cable connection end. Slowly peel back the protective liner from the PADS.

4. Place the posterior pad on the left side of the patient's back, behind the heart in the intrascapular area. Apply the pad to the patient's skin. Do not place the pad over bony prominence of the spine or scapula.



5. Place the pad on the left side of the patient's chest. The upper edge of the pads should be just below the nipple and apply to the patient skin.

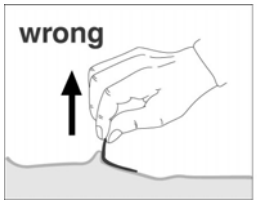
6. Starting from one edge, firmly press the pad onto the patient's skin to eliminate air pockets between the gel surface and the skin.

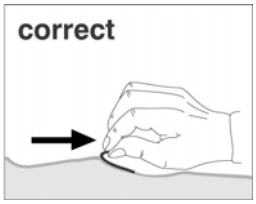
7. Connect pads cable to the pads.

CHANGING PADS

The pads must be changed after a therapy sequence (defibrillation or one (1) hour of continuous pacing) is delivered.

Turn off pacing and make sure Channel 1 lead source is not “Pads”.
Exit Manual Mode or Semi-auto Shock before disconnecting pads.
Disconnect pad connector from the Responder 2000.
Remove pads from the patient





Prep skin and attach new pads to the patient, in a slightly different location to avoid irritation or burns.
Attach pad connector to Responder 2000.
Select desired mode from the Systems Menu.

PADS OFF NOTIFICATION

For the pads off notification, check the following:

- Check for proper skin preparation
- Check for adequate pad contact between the pad and the patient’s skin
- Check for expired / dry pads
- Check to see that the pads are properly connected the Responder 2000.
- Change pads

PADS SHORTED NOTIFICATION

Check to see if pads are placed too close to each other and, if so, separate the pads ensuring that there is enough distance between the pads
Change pads

NOTE: Anterior / Posterior pads placement may alleviate a PADS SHORTED message.

NOTE: If impedance at the pads/paddles is too low to shock the patient, the ECG in the display will automatically switch from pads/paddles ECG to ECG II, if this feature is activated from the settings. To go back to pads/paddles ECG you have to switch back manually.

WARNING: Due to the unique impedance characteristics of the patient, the Responder 2000 may not be able to shock the patient.

USING ECG ELECTRODES

The ECG electrodes are required for operating the Responder 2000 in external demand pacing mode, ECG Monitoring mode, and during Semi-Auto mode..

In order to ensure proper demand pacing, the Responder 2000 requires a high quality surface ECG signal between the patient's skin surface and the ECG electrode. Standard 3-lead or 5-lead configuration is used to monitor the patient's electrocardiogram.

NOTE: The skin is a poor conductor of electricity, therefore preparation of the patient's skin is important to facilitate good electrode to skin contact. When cleaning the patient's skin, NEVER use alcohol or tincture of benzoin, as this increases skin resistance.

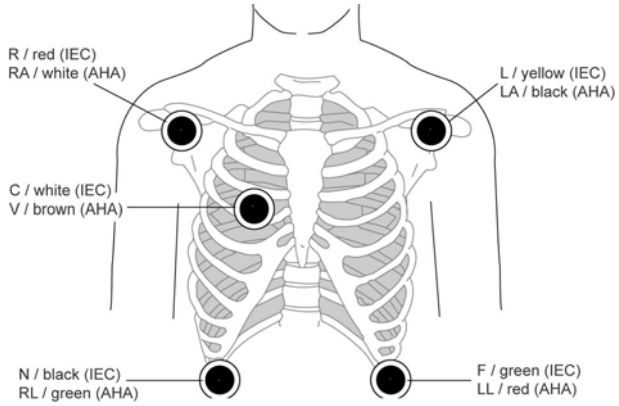
APPLYING ECG MONITORING ELECTRODES

1. Attach the ECG patient cable lead wires to the ECG electrodes. The lead wires are color coded according to AHA or IEC standards.
2. Plug the ECG patient cable into the ECG input connector (green) located on the front panel of the Responder 2000.
3. Prepare the patient's skin according to the Patient Preparation section in this manual.
4. Peel the backing off the electrodes and press the electrodes firmly onto the patient's skin.

USING ECG ELECTRODES (CONTINUED)

3-Lead Placement
RA/R placement: Directly below the clavicle and near the right shoulder
LA/L placement: Directly below the clavicle and near the left shoulder
LL/F placement: On the left lower abdomen

5-Lead Placement
RA/R placement: Directly below the clavicle and near the right shoulder
LA/L placement: Directly below the clavicle and near the left shoulder
RL/N placement: On the right lower abdomen
LL/F placement: On the left lower abdomen
V/C placement: On the chest; the position depends on the required lead selection.



5. Select a site where the signal will not be interfered with by either movement or bones. Avoid touching the tape and electrode gel.

6. Make sure there is adequate space (approximately 3 cm) between the pads and the ECG monitoring electrodes.

7. The various ECG leads can be individually selected and viewed on the LCD screen. The ECG Monitoring mode is the ideal screen for viewing any of the ECG leads without therapy intervention.

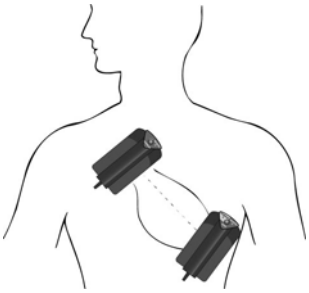
USING EXTERNAL PADDLES

To defibrillate using external paddles:

WARNING: Use only paddles specified in Section 7 of this manual. The use of unapproved equipment may cause the Responder 2000 to malfunction and may hinder patient treatment.

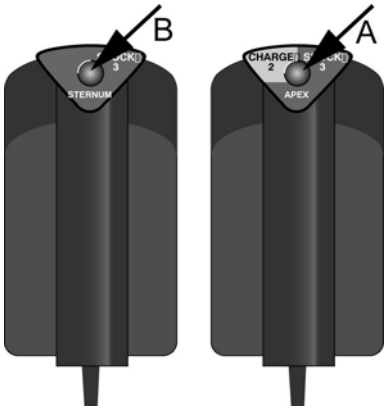
WARNING: Risk of Skin Burns / Equipment Damage — Do not apply the paddles over sternum or clavicle, nipples, implanted pacemaker or defibrillator devices.

1. Remove the Paddle Set from the Paddle cradles by pulling the paddles outward and out of the paddle docks.
2. Carefully dry the paddles and handles in particular, if they are damp or wet.
3. Apply electrode gel to the paddles. Do not distribute electrode gel by rubbing the paddles together.
4. Apply paddles to the patient's bare chest, using the anterior-lateral placement (or in accordance with your organization's protocol). Apply the paddles on the patient's thorax such that the greatest possible amount of energy flows through the myocardium. The imaginary line connecting the paddle centers should be identical with the cardiac median line.
5. Press the paddles firmly onto the thorax (the ECG appears on the monitor screen).



6. Initiate energy storage with the button on the APEX paddle (a).
   When the selected energy is stored, the device emits an audio signal and the message "Stand Clear, Push Paddle Shock" appears.

7. Now trigger the shock within 30 seconds. To do so, simultaneously press the buttons (A) and (B) on the paddles.

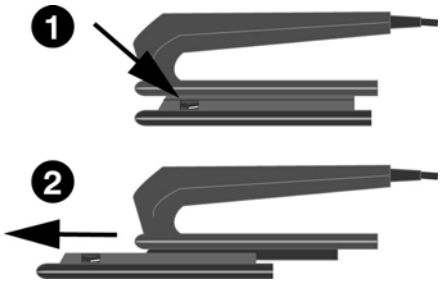


NOTE: When the patient is a child under 8 years of age or weighs less than 55 lbs (25 kg), the Responder 2000 should be used with Pediatric Defibrillation paddles and pediatric energy protocols. These paddles are integrated into the standard paddle set and are available by removing the adult contact plates off the paddles.

The paddles have two different contact surfaces; a large one (can be removed) for the defibrillation of adults and a smaller one for the defibrillation of children.

Remove the large contact surface for pediatric use:

- Press on the lock button 1
- Slide the contact surface 2 towards the front and take it off the paddle.
- When re-installing it, the large contact surface must audibly click into place.



USING INTERNAL PADDLES (SPOONS)

To defibrillate using internal paddles:

WARNING: Shock Hazard – Always switch off the device before exchanging the defibrillation electrodes and internal spoons.

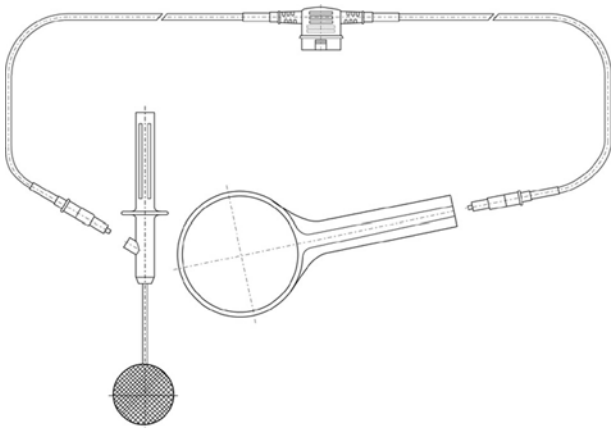
NOTE: If you are using internal electrodes with the Responder 2000, defibrillator charging and shock delivery must be initiated with corresponding buttons on the front panel of the Responder 2000.

NOTE: The selectable energy when using internal paddles is as follows: 2, 3, 5, 7, 10, 15, 20, 30, and 50 Joules

NOTE: Internal defibrillation is only allowed in Manual Mode!
If Semi-Auto Mode is selected while spoons are attached, the Responder 2000 will automatically switch to Manual Mode.

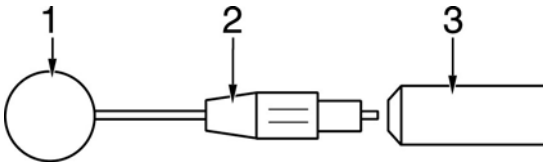
1. Setup internal paddles according to instructions supplied with them.
2. Connect the internal paddles to the paddle dock on the back of the Responder 2000.
3. Apply paddles to the patient's heart.

Spoon-shaped electrodes are used for internal defibrillation. Their contact surface must match the dimensions of the heart. The spoons must make full contact with the heart. There is a choice of 3 different spoon sizes. You can use either two spoon electrodes or one spoon electrode and one external counter electrode for defibrillation.
Sterilize internal electrodes before each use (see section "Maintenance & Service").



INSERTING THE SPOON ELECTRODE

- Screw the counter nut **2** onto the electrode as far as it will go.
- Screw the contact paddle **1** into the handle as far as it will go, then bring it into the appropriate position.
- Now fix the contact paddle by screwing the counter nut **2** tight against the handle **3**.



DEFIBRILLATOR APPLICATION GUIDELINES

Observe the following guidelines to ensure successful and safe defibrillation. Otherwise the lives of the patient, the user and bystanders are in danger.

WARNING: Defibrillating a patient with normal heart rhythm may induce ventricular fibrillation.

WARNING: Position the patient flat on a hard surface where he is electrically insulated. The patient must not be allowed to come into contact with metal parts to prevent unwanted pathways for the defibrillation current which may endanger the assistants. For the same reason, do not position the patient on wet ground (rain, accident in swimming pool).

WARNING: Do not allow the defibrillation electrodes to come into contact with other electrodes or metal parts which are in contact with the patient.

WARNING: The patient's chest must be dry, because moisture can cause unwanted pathways for the defibrillation current. After use of flammable skin cleansing agents, wait until they have completely dried.

WARNING: The operator and all assistants must be briefed regarding the preparations for and execution of defibrillation. All tasks must be clearly assigned.

- Immediately prior to the shock: interrupt heart massage and artificial respiration, disconnect tube connections, and warn bystanders.
- Ensure that no conductive connection between the patient and bystanders exists during defibrillation.
- Before delivering the shock, verify that the charged and selected energies are the same.

WARNING: Shock Hazard
Always switch off the device before exchanging the defibrillation electrodes.

WARNING: Pacemaker Patients
Defibrillating a patient with an implanted pacemaker is likely to impair the pacemaker function or cause damage to the pacemaker.
For this reason:
- Select the smallest energy level possible for the application,
- Do not apply the defibrillation paddles in the vicinity of the pacemaker,
- Have an external pacemaker at hand,
- Check the implanted pacemaker for proper functioning as soon as possible after the shock.

WARNING: Equipment Damage
Disconnect transducers and devices that are not defibrillation-proof from the patient before delivering the shock.

WARNING: Equipment Damage
Do not defibrillate the patient with a second defibrillator, while defibrillation electrodes (paddles, pads) of the first device are applied. If the use of a second defibrillator is inevitable, disconnect the electrodes from the first device or remove them from the patient**.**

DEFIBRILLATION MODES

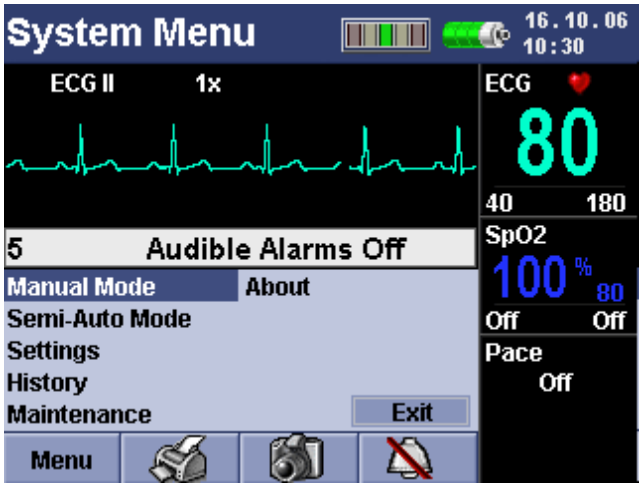
The Responder 2000 has two (2) modes of defibrillation, each with a customized display view. The modes are as follows:

Manual Mode	Operator manually selects energy level appropriate for the patient's age, manually charges the unit, and manually delivers therapy to the patient. In this mode, energy can be selected manually or by using the auto-sequence energy settings. In this mode, shock can be delivered in Synchronous (Sync) with a R-wave by selecting the Sync Button. If Sync is selected, the Responder 2000 will attempt to synchronize the shock. If it is unable to synchronize within 2 seconds, it will not deliver the shock. Default for manual mode is No Sync.
Semi-Auto Mode	In this mode, the operator can analyze the patient's heart rhythm. Upon detection of a shockable rhythm, the Responder 2000 will automatically charge and prompt the operator to press the shock button to allow therapy to be delivered to the patient. In Semi-Auto Mode, the Responder 2000 charges the unit to user preset energy settings.

CHOOSING A DEFIBRILLATION MODE

The Responder 2000 default operating mode is **Manual** mode. To change the default mode, refer to Section 4 on Configuring the Responder 2000.

1. To choose an operating mode, open the **System Menu**.



2. Select the desired mode: Manual Mode or Semi-Auto Mode.

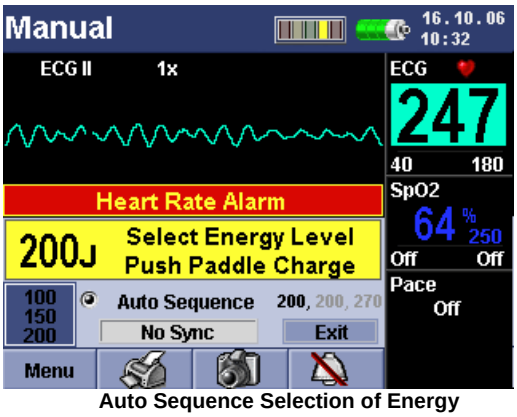
3. Ensure that the ECG monitor waveform shown in Channel 1 is set to the correct input source and gain. If not, follow the directions given in ***Setting the ECG Source and Gain*** in this chapter to adjust.

MANUAL MODE

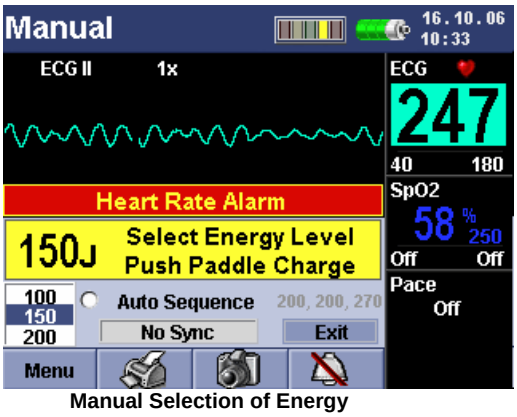
Operator manually selects energy level appropriate for the patient's age, manually charges the unit, and manually delivers therapy to the patient. In this mode, energy can be selected manually or by using the auto-sequence energy protocol. Default method of delivering therapy in the manual mode is No Sync, namely, therapy is delivered as soon as the shock button is pressed. If the user chooses the Sync mode in the Manual Mode screen, therapy will not be delivered if the device cannot synchronize with the patient's R-wave within 2 seconds after the shock button is pressed.

TO USE MANUAL MODE

Manual Mode can be selected from the System Menu or by pressing the Manual button. If Manual Mode is set as the default mode, the Responder 2000 will power up in Manual Mode after turning the Responder 2000 on. It will then flash the yellow Charge button.



Auto Sequence Selection of Energy



Manual Selection of Energy

1. To select the desired energy level appropriate for the patient's age, turn Rotary Selector Knob counterclockwise to go up and down the list. The operator will be able to select the following energy values:

   PRECAUTION: Select the energy level appropriate for the patient's age. The Responder 2000 does not select the energy or shock sequences based on the defibrillation pads connection.

   For pads and paddles:

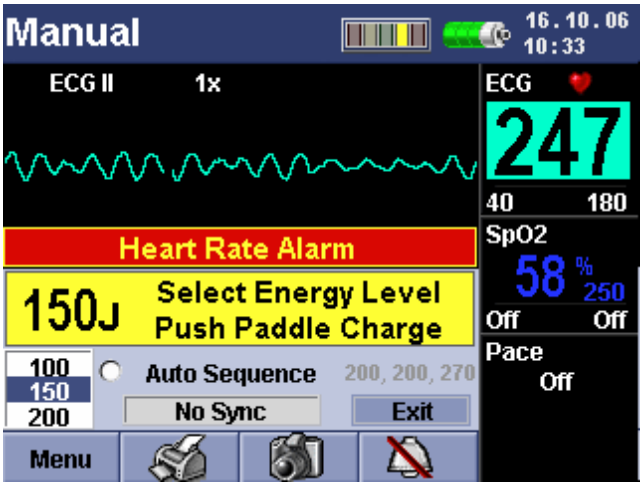
   2, 3, 5, 7, 10, 15, 20, 30, 50, 70, 100, 150, 200, and 270 Joules

   For internal paddles/spoons:

   2, 3, 5, 7, 10, 15, 20, 30, and 50 Joules

TO USE MANUAL MODE (CONTINUED)

2. After selecting desired energy, press the Rotary Selector Knob.
3. Push the Charge button.
4. Warn bystanders to stand clear of the patient. Ensure that you do not touch the patient.
5. After the Responder 2000 is charged, push and hold the Shock button(s) until therapy is delivered.



6. The message Shock Delivered displays for eight (8) seconds once the shock has been delivered.
7. At any time during the manual defibrillation sequence, the operator can change the energy setting or exit the mode completely by turning the Rotary Selector Knob and pressing Exit OR by pushing the Manual button.

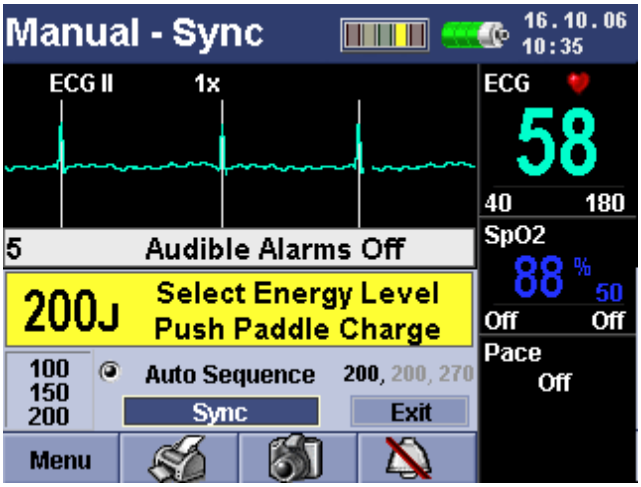
NOTE: The operator has thirty (30) seconds to deliver therapy before the Responder 2000 disarms and aborts therapy.

NOTE: Alarm Silence symbol is displayed, indicating that no audible tone warnings will be heard, only written warning message will be displayed on the graphics display.

NO SYNC/SYNC OPTION

The Responder 2000 has a No Sync/Sync Option available in Manual Mode only. If No Sync is selected, shock is delivered immediately. When Sync is selected, full length R-wave sync marks are drawn on display and shock delivery is synchronized with the R-wave. No Sync is selected by default.

1. Turn the Rotary Selector Knob to No Sync/Sync toggle button
2. Press the Rotary Selector Knob to select Sync option



PRECAUTION: Observe the ECG rhythm. Confirm that the full length sync bar appears near the middle of each QRS complex. If the sync bars do not appear or are displayed in the wrong locations change the lead source.

NOTE: Every time after a Sync Shock is delivered; the device resets to "**No Sync".**

NOTE: Select a lead that provides a unipolar R-wave with a minimum amplitude of 1 mV and a low-amplitude T-wave.

AUTO SEQUENCE

In **Manual Mode**, there is also an **Auto Sequence** option. In Auto Sequence, three energy levels can be pre-set. When this option is selected, the Responder 2000 automatically selects the first pre-set energy and prompts the operator to push the **Charge** button. After the Responder 2000 is charged, it will prompt the operator to push the **Shock** button(s). After a shock is delivered, the Responder 2000 automatically selects the next energy level. After all three pre-set shocks have been delivered; the Responder 2000 selects the last energy level. All shocks after the third shock will be at that level.

NOTE: In Auto Sequence if the user wants to deliver a Sync Shock, Sync must be selected individually for all shocks in Auto Sequence.

SEMI-AUTO SHOCK MODE

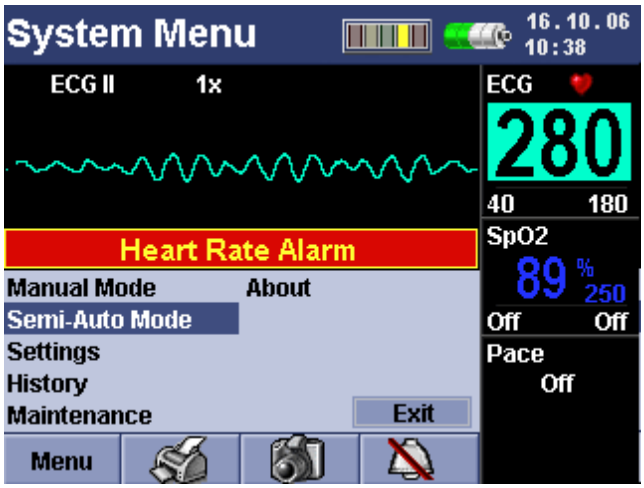
In this mode, the Responder 2000 will analyze the patient's heart rhythm. Upon detection of the shockable rhythm, the Responder 2000 will automatically charge and prompt the operator to press the shock button to allow therapy to be delivered to the patient.

Use of spoons is not be allowed in Semi-Auto Shock Mode. If spoons are attached to the Responder 2000 during power on, selection of Semi-Auto Mode, or while already in Semi-Auto mode, the device will automatically switch to Manual Mode immediately. The Message Area will display "Switched to Manual Mode" for six seconds.

TO USE SEMI-AUTO SHOCK MODE

Upon the detection of a shockable cardiac rhythm, the Semi-auto Shock mode provides the ability to automatically charge up to three (3) defibrillation shocks in a pre-programmed auto sequence and advise the operator when to manually press the flashing shock button(s) to deliver therapy.

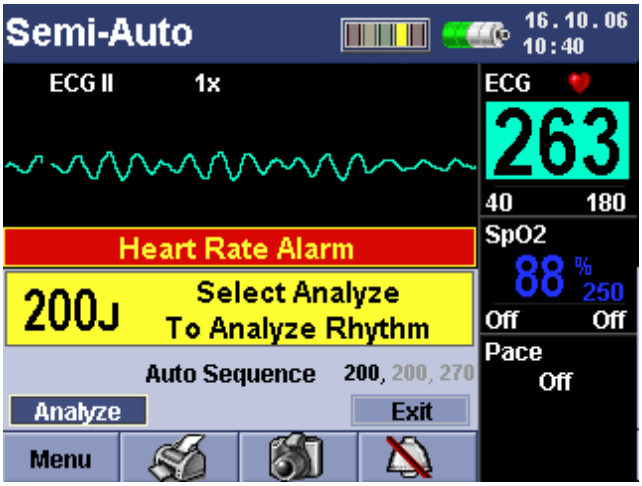
Semi-Auto Shock mode can be selected from the System Menu. If Semi-Auto Shock mode is set as the default mode, the Responder 2000 will automatically go into Semi-Auto Shock mode after turning the Responder 2000 on.



NOTE: Semi-Auto Mode is not allowed with Paddles as Channel 1 Source.

TO USE SEMI-AUTO SHOCK MODE (CONTINUED)

1. Press the Rotary Selector Knob to Analyze.



2. If a shockable rhythm is detected, the Responder 2000 will automatically charge to the appropriate energy level. The sequence starts with the first displayed value then increments through the three increasing values.

3. When the charge is complete, the operator is prompted to push Shock button(s).

NOTE: The operator has thirty (30) seconds to deliver therapy before the Responder 2000 disarms and aborts therapy.

4. After three (3) shocks in Semi-auto Shock mode, the Responder 2000 continues to use the last delivered energy.

ECG MONITORING

This section describes the basic ECG monitoring functions of the Responder 2000.

The Responder 2000 can be used for ECG monitoring. The monitoring function allows the operator to monitor through:

- Pads
- 3-lead ECG Electrodes
- 5-lead ECG Electrodes

If both pads and monitoring electrodes are connected, monitoring allows you to select a lead from the 3-lead, 5-lead ECG source, or to monitor through the pads.

Configurable heart rate and arrhythmia alarms clearly communicate patient status, both audibly and visually.

See Setting the ECG Source and Gain in this section for changing these settings.

ACTIVATING AND DEACTIVATING FILTERS

Activating muscle and AC line filters makes the displayed ECG insensitive to AC interference and muscle tremor. However, the filters alter the ECG signal, and a filtered signal is not suitable for diagnosis (displayed or printed ECG).

NOTE: Active filters will alter the ECG signal. Switch off the filters to obtain a diagnostic ECG.

NOTE: ECG signals acquired with pads, paddles, or spoons cannot be used for diagnostic purposes.

MONITORING HEART RATE

WARNING: No Asystole Alarm
The defibrillator gives asystole alarm only when the heart rate falls below the low HR limit. Therefore, do not disable the low HR limit.

WARNING: Incorrect HR / No HR Alarm
In the presence of arrhythmias and morphological changes of the ECG, the device may not be able to calculate the correct heart rate. Beats may be counted twice or may be ignored

NOTE: The defibrillator can be set up to automatically activate the alarm tone on power up. The default alarm limits can also be adjusted in the setup menu.
During patient transport the device may fail to identify arrhythmias due to motion artifact.

The default heart limits are 40 and 180 bpm and the audio alarm is disabled. The audio alarm can be enabled permanently from the setup menu.

The defibrillator reports an alarm condition if the HR exceeds one of the alarm limits for more than 10 seconds:

- The audio alarm sounds (configurable)
- The recorder starts (configurable)
- The alarm is indicated on the display

When the parameter reading returns to normal range, the audio alarm stops.

For information on setting and changing alarm parameters, refer to chapter *Responding to Alarm* and chapter *Adjusting Heart Rate Alarm Limits* in this section.

MONITORING PACEMAKER PATIENTS

When monitoring the heart rate of pacemaker patients, only the patient's QRS complexes must be counted and pacer pulses must be rejected. For this purpose, the Responder 2000 has an electronic pacer pulse suppression algorithm which rejects the pacer pulses so they are not counted as QRS complexes. Depending on the pacemaker model used and on the position of the electrodes, the compensation pulse following every pacer pulse may be considered as a QRS complex. Every pacemaker must provide an oppositely charged current (reverse current) after delivering a pacing pulse. In this situation and when the pacer pulse is ineffective, the displayed heart rate may be misinterpreted, and the device will not give alarm in the presence of bradycardia or asystole.

Always monitor pacemaker patients by means of separate ECG electrodes and not via the defibrillation electrodes.

As an additional precaution, monitor pacemaker patients by means of pulse oximetry.

It depends on the pacer pulse parameters, whether or not the compensation pulse is counted as a QRS complex.

For pacemaker patients, the ECG R-wave signal size should be greater than 1 mV.

WARNING: No HR Alarm — If several adverse conditions exist at once during monitoring of pacemaker patients, the possibility that pacer pulses are interpreted (and counted) as QRS complexes should be considered. Therefore, pacemaker patients should always be watched closely.

NON-INVASIVE PACING (OPTION)

This section describes the noninvasive transcutaneous pacing option available with the Responder 2000 and describes how to perform pacing.

Application and Functional Description
The transcutaneous pacemaker of the Responder 2000 is used for external (transchest) cardiac stimulation in emergencies. It is applied temporarily in cases of acute arrhythmia, such as cardiac arrest or Stokes-Adams attacks. Specific forms of bradycardia and tachycardia can also be treated with the pacemaker.
The pacemaker offers two modes of operation: demand and fixed-rate pacing ("Fix").
The pacer pulses are delivered via the adhesive defibrillation electrodes (pace pads). Electrodes for adults and for children can be used. Separate ECG electrodes must be applied for acquisition of the ECG signal.

WARNING: For treatment of patients with implantable devices such as permanent pacemakers or cardioverter defibrillators, consult a physician and the instructions for use provided by the device's manufacturer.

WARNING: Use demand mode pacing whenever possible. Use fixed mode pacing when motion artifact or other ECG noise makes R-wave detection unreliable or when ECG monitoring electrodes are not available.

PRECAUTION: The maximum duration of pacing is recommended at one (1) hour. If patient condition requires prolonged continuous pacing it is recommended that pads should be replaced to ensure maximum patient benefit. Prolonged pacing particularly in neonates or adults with severely restricted blood flow, may cause burns. Periodic inspection of the underlying skin is recommended.

PRECAUTION: Check that pad adhesive is intact and undamaged.

PRECAUTION: If the battery is removed while pacing and there is not AC Power, the pacing settings need to be re-set when the battery is inserted again.

NOTE: The message "Please wait" will be displayed during the period when the Responder 2000 is not pacing, because of change of lead. The Responder 2000 will not pace during this time.

WARNING: Shock Hazard
Due to their functional requirements, pacemakers operate with high voltages and are therefore equipped with specially protected outputs. Nevertheless, it is important not to touch live contacts with conductive metal objects, such as tweezers, as long as the pacemaker is operating. Currents exceeding 10µA may induce ventricular fibrillation,
if they flow through the heart. Observe the following sequence of operating steps when turning the pacemaker on and off.

TO USE PACING MODE

To Enable Pacing:

1. Apply ECG electrodes to patient.
2. Connect ECG electrodes to the device.
3. Turn on the Responder 2000.
4. Check ECG and vital signs
5. Attach pace pads to patient.
6. Connect pace pads to the Responder 2000.
7. Use Rotary Selector Knob to move focus Pacing Info box, at the display's lower right.
8. Select the Pacing Info box. If pacing is not enable, the Pacing Info box is not selectable.
9. Use Rotary Selector Knob to traverse though selectable items.
10. Turning clockwise, the following items should be selectable, in order, wrapping around:
    a) Pacing Type (Fixed, Demand), Default is Demand.
    b) PPM (30-180 PPM, increments of 5), Default is 60 PPM
    c) Exit Pacing Info Box ("x" in corner)
    d) Pacing On/Off/Pause (Pause is only available when Pacing is turned On)
    e) Pacing Current (0mA-140mA, increments of 5). This option is only selectable when pacing is turned on.
11. Turn the Rotary Selector Knob to turn on the pacing.
12. When Pacing is turned on, focus automatically goes to the Pacing Current selection. Set desired pacing current.
13. Turn the rotary knob to select pacing rate and set desired options for pacing rate.

To Stop Pacing:

1. Turn the pacemaker OFF
2. Disconnect pace pads from the Responder 2000.
3. Remove pace pads from patient.
4. If monitoring of the patient is no longer required, turn off the Responder 2000.
5. Remove ECG electrodes from patient.

GUIDELINES FOR THE APPLICATION OF EXTERNAL PACEMAKERS

All electrical devices that deliver energy to patients in any form or have an electrically conductive connection to the patient present a potential hazard.

The user is responsible for the safe application of the devices. Observance of the instructions given in the operator's manual and of the guidelines below is therefore of utmost importance:

a) Pacemaker must only be used under the supervision of qualified and authorized staff.

b) The prerequisite for safe application is the use of intact devices in rooms that meet the applicable requirements. Expert knowledge, good organization and special care in selecting the technical installation as well as regular maintenance are required to ensure such operating conditions.

c) Medical electrical devices such as the Responder 2000 must only be handled by persons who are trained in the use of such equipment and are capable of applying it properly.

d) Before using the device, the operator is obliged to verify that it is in correct working order and operating condition.

e) It is assumed that the patient's ECG is being monitored to be able to assess the effect of pacing. Furthermore, at least one of the persons present must be trained in the use of the defibrillator.

f) Check the defibrillator performance before using the pacemaker on a patient.

g) The pulse current output of the pacemaker is ungrounded. This ensures that the pacer current only flows between the pacemaker electrodes.

h) If the patient needs to be defibrillated while the pacemaker is on, the pacemaker first must be turned off. After delivery of the defibrillation shock you have to restart the pacemaker and adjust the pacemaker settings.

i) Use only the electrodes and cables listed in section 7 "Accessories".

DEMAND PACING

WARNING: The pacer pulses are delivered via the adhesive defibrillation electrodes. Separate electrodes must be applied for acquisition of the ECG signal. It is imperative to apply the ECG electrodes before turning the pacemaker on. Then wait for a few minutes before pacing to allow the electrode gel to penetrate the skin and reduce the electrode skin contact impedance. The pacemaker can be enabled only when adhesive electrodes are connected.

In demand mode, the pacemaker does not deliver pacing pulses as long as the patient's intrinsic heart rate exceeds the set pacing rate. When the heart rate drops below the pacing rate, the pacemaker starts emitting stimulation pulses. This can only be ensured by continued electronic monitoring of the ECG. The necessary synchronization pulses are automatically sent to the pacemaker.

PRECAUTION: Pacemaker malfunction due to poor ECG signal quality
As a general rule, check the ECG signal quality before turning the pacer on. In the presence of excessive electrode-skin contact impedance, the signal quality may drop to a level which the Responder 2000 interprets as a lead fail condition. As a result the device will display a dashed line and switch from demand pacing to the fixed-rate pacer mode or to pacer PAUSE mode. If you wish to continue pacing in the fixed-rate mode, it is mandatory to verify the success of stimulation by checking the patient's pulse. If you wish to resume demand pacing, you first have to improve the electrode skin contact impedance. Then switch the pacer manually from PAUSE to ON. The other pacer parameters will be kept.

NOTE: Even in unfavorable situations, the electrode gel will penetrate the patient's skin in 5 to 7 minutes, reducing the electrode-skin contact impedance. If this is sufficient to improve the signal quality, pacing in the demand mode will then become possible.

The demand mode is the recommended pacing mode when the patient is at risk of developing bradycardia or even cardiac arrest as a result of a critical event. As the pacemaker function is controlled by the patient's ECG, the harmful competition between intrinsic and external stimulation which could induce ventricular fibrillation is excluded.

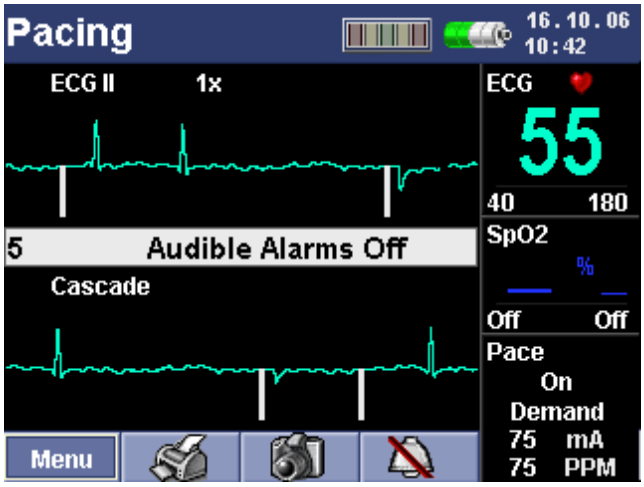
1. Check that the ECG electrodes and the pace pads are correctly applied and connected to the device.

2. Turn the Rotary Selector Knob to turn on the pacemaker.

3. Check the ECG signal quality.
   If the signal quality is not adequate, either wait until the electrode gel has reduced the electrode skin contact impedance or select another lead, or reapply the electrodes exactly as described.

The device defaults to the Demand mode and selects a pacer rate of 60 PPM (configurable).

1. Select the Pacing Info Box by turning the Rotary Selector Knob.
2. Turn pacer on.
3. Select a low pacer current output, e.g. 20mA
4. Select the required pacer rate.
5. Now increase the pacer current output slowly until the heart reliably responds to the stimulation.
6. Increase the pacer current output another 5 mA to ensure continued stimulation.
7. Verify the stimulation by watching the ECG on the display.
8. You can pause the stimulation and resume pacing with the same settings by turning focus to the “On” –field and selecting “Pause” with the Rotary Selector Knob.
9. After therapy, turn off the pacemaker before removing the pace pads carefully.



FIXED-RATE PACING

WARNING: During fixed-rate pacing, heart rate and heart rate alarms are suppressed. Therefore, the operator shall check for the patient's pulse rate, not the heart rate.

PRECAUTION: The pacer pulses are delivered via the adhesive defibrillation electrodes. Separate electrodes can be applied for acquisition of the ECG signal. Without ECG electrodes the ECG cannot be displayed.
In fixed-rate mode, the device delivers pacing pulses at the selected rate and current. The selected rate remains constant and is not affected by intrinsic actions of the patient's heart. This is the preferred mode for cases of cardiac arrest.

NOTE: The default pacer rate can be configured. End the therapy as described under "Demand Pacing" above.

1. Check that the ECG electrodes and the pace pads are correctly applied and connected to the device.
2. Use the Rotary Selector Knob to turn on the pacemaker. The device defaults to the Demand Mode, if separate electrodes are applied and selects a pacer rate of 60 PPM (configurable).
3. Turn the Focus to the Demand field to activate the fixed-rate pacing mode by selecting Fix Mode, using the Rotary Selector Knob.
4. Select the required pacer rate.
5. Now increase the pacer current output slowly until the heart reliably responds to the stimulation.
6. Increase the pacer current output another 5 mA to ensure continued stimulation.

PULSE OXIMETRY (OPTION)

Pulse Oximetry (SpO_2) monitoring is one of the tools available to assist in assessing a patient's cardiac and respiratory systems. Pulse oximetry is a noninvasive method of continuously measuring oxygen saturation (SpO_2) in arterial blood. The resultant SpO_2 reading indicates the percentage of hemoglobin molecules in the arterial blood which are saturated oxygen.

The Responder 2000 SpO_2 can be monitored in all operating modes.

A pulse oximetry sensor sends light through patient tissue to a receiver on the other side of the sensor.

When the SpO_2 sensor is connected; the waveform can be selected for display in Channel 2 of the dynamic graphic display area.

1. Turn the Rotary Selector Knob until the Channel 2 source wave heading is highlighted and press the Rotary Selector Knob.

2. Turn the Rotary Selector Knob until SpO_2 displays and press to select. The waveform changes to show the SpO_2 trace.

WARNING: Do not rely solely on SpO_2 readings; assess the patient at all times. Inaccurate measurements can be caused by:

- Incorrect sensor application or use.
- Significant levels of dysfunctional hemoglobins (such as carboxyhemoglobin or methemoglobin)
- Injected dyes such as methylene blue, or intravascular dyshemoglobins such as methemoglobin or carboxyhemoglobin
- Exposure to excessive illumination such as surgical lamps (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight.)

NOTE: The SpO_2 alarms do not generate a printout.

NOTE: The SpO_2 alarms can be cleared either by changing the Channel 2 Source to Cascade or by reconnecting the SpO_2 sensors.

NOTE: Use only sensors that are recommended in Section 7 of this manual.

WARNING: No Alarm
Under certain conditions the device may not be able to identify a signal disturbance when monitoring the patient. In this situation artifacts are capable of simulating a plausible parameter reading, so that the monitor fails to sound an alarm. In order to ensure reliable patient monitoring the proper application of the probe and the signal quality must be checked at regular intervals.

APPLICATION TIPS

General Tips

- Use only the probes listed in chapter 7 "Accessories". Apply the probes as described in their instructions for use. Carefully observe all information and cautions given in these instructions.
- Take care that the probe does not exert too much pressure when applied to avoid erroneous readings and blistering. Inadequate oxygen supply to the skin, not heat, causes blisters.
- Change the probe site at least every 24 hours to allow the skin to breathe.
- Be careful to ensure continued circulation at the probe site.
- Incident light may cause inaccurate readings. Cover the measuring site with a cloth, if necessary.
- It may not be possible to measure SpO2 values, if cardiac output is determined at the same time by means of the dye dilution technique.
- It may not be possible to measure SpO2 values or the pulse rate, if the circulation is impaired (e.g. by a blood-pressure cuff or by an extremely high vascular resistance).
- Remove nail polish and artificial finger nails before applying the probe. Both may lead to inaccurate readings.
- Do not apply the finger probe to the same arm as the blood-pressure cuff.

To minimize motion artifact

- Use a new probe with fresh adhesive backing
- Move the probe to a less active site
-

When monitoring SpO_2 during electrosurgical intervention, take care that

- The device is powered from the internal battery or from a different power circuit than the electrosurgical unit
- The ground pad is close to the surgical site
- The probe is applied as far from the surgical site, the ground pad and the electrosurgical unit as possible.

In the presence of AC line interference

- When interference signals from the power line are present, square waves may be displayed instead of the plethysmogram. In this situation we recommend to disconnect the device from the power line and operate it on battery power.

PRINTING

The Responder 2000 allows the operator to print the channel waveform and associated information. The print starts with waveform data four (4) seconds prior to the initiation of the print sequence and will automatically stop after twenty (20) seconds (default) or run continuously.

TO PRINT

NOTE: Verify printer has adequate paper on its roll for use.

Rotate the Rotary Selector Knob until the Print icon highlights and press to initiate printing. A single press starts the print sequence. While printing, a second press of the Rotary Selector Knob stops printing the record information.

The printer will annotate the following information along the length of the print out.

1. BPM
2. SpO_2
3. Pulse
4. Line Filter
5. Muscle Filter
6. Date
7. Time
8. Paper Speed
9. Cause (Of Printout)
10. Delivered (Energy from Defib)
11. Facility
12. Channel 1 Source
13. Selected and delivered energies (When defibrillation is used.)
14. Pacing rate, mode and current (When Pacing is enabled.)

At the end of the print out, the following information is printed:

a. Patient Name:
b. Patient Birth Date:
c. User Name:
d. Comments:
e. Date:
f. Time:
g. Selected: (Energy) or Mode: (Fixed or Demand)
h. Delivered: (Energy) or Rate and Current
i. ECG Alarm Low:
j. ECG Alarm High:
k. SpO_2 Alarm Low:
l. SpO_2 Alarm High:

NOTE: The ECG channel waveform will be printed with fixed gain and does not depend on the gain set for the displayed ECG.

NOTE: If activated in the settings, the printer starts automatically with each new alarm activation. Active printouts will be interrupted immediately.

NOTE: If activated in the settings, the printer starts automatically with each “Shock Recommended” message in the Semi-Auto Mode.

SNAPSHOT

The Snapshot feature takes a snapshot of Channel 1 or Channel 2 depending on the cursor position at the time of selection (if cascaded). It will then display it in the region of Channel 2. Snapshot is saved as an event and can be printed from the Event History log. Snapshot saves 20 seconds of ECG information. (4 seconds of history at the time of selection and 16 seconds of data after the selection. When Snapshot is selected, the camera icon flashes indicating Snapshot is selected. To turn off Snapshot, select the Snapshot icon again. To generate the next snapshot waveform event, the operator should wait at least 20 seconds.

TO TAKE A SNAPSHOT

1. Turn the Rotary Selector Knob to the camera icon and push to take a snapshot of Channel 1 and have it displayed in Channel 2. Channel 1 continues to monitor in real time.

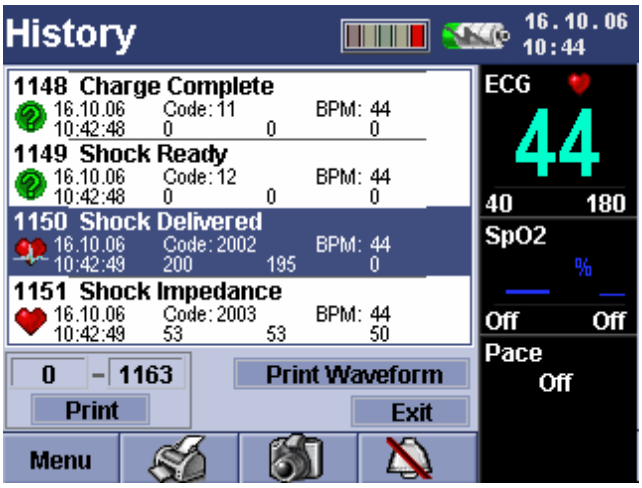
HISTORY MENU

From the history menu the operator can view the event log and patient trends.

EVENT LOG

The Responder 2000 logs patient events, operator actions, and system errors and warnings. This information can be viewed or printed.

- Logged Events show the name, event code, time of occurrence and associated information with the event.
- Up to 5000 of the most current events can be viewed. The operator can select a range of events to print.
- Patient events also store their associated ECG waveform, which can be printed from the event log menu. Only the forty (40) most current event waveforms are saved.



PATIENT TRENDS

Trend data of Heart Rate and SpO_2 Saturation is available in 45 minute or 9 Hour intervals. The Patient Trends need to be cleared every time a new patient is connected. A vertical line with a pointed arrow on the trend indicates a power cycle. The beginning and ending date/time are printed on the trend data printout.

RESPONDING TO ALARMS

When an alarm condition occurs and an alarm is indicated, visually and audibly, there are several ways to respond. Initially:

1. Attend to the patient

2. Identify the alarm(s) indicated

   Alarms are grouped into three categories:

   - **High priority** (Warning - requires immediate action)
   - **Medium priority** (Precaution)
   - **Low priority** (Advisory)

Depending on their category, alarms have different visual and/or audible indicators. Higher priority alarm(s) overrides any medium or lower priority alarms.

HIGH PRIORITY ALARMS

High Priority Alarms are generated by the following:

- ECG is higher or lower than the alarm thresholds.
- SpO_2 % saturation is high or low
- If patient has a shockable rhythm after the user selects to analyze the heart rhythm
- Pads are off during pacing
- ECG leads are off during demand pacing
- Battery low indication

10-beep High priority audible alarm, repeating every 5 seconds.

(Beep-beep-beep…beep-beep…… beep-beep-beep…beep-beep)

These alarms do not occur when the Responder 2000 is initially powered on.

MEDIUM PRIORITY ALARMS

Med Priority Alarms are generated by the following:

- Pads off
- Leads off
- Battery Low

3-beep Medium priority audible alarm, repeating every 4.25 seconds

(Beep-beep-beep)

These alarms do not occur when Responder 2000 is initially powered on.

LOW PRIORITY ALARMS

Low Priority Alarms are generated by the following:

- Therapy system errors
- SPO_2 sensor off

2-beep Low priority audible alarm, repeating every 17.5 seconds

(Beep-beep)

These alarms do not occur when Responder 2000 is initially powered on.

VISUAL ALARM DISPLAYS

- For patient related alarms the associated on-screen value highlights and flashes
- To attract attention, the background edge of the highlight flashes every second while the alarm is active.

AUDIBLE ALARMS

The Responder 2000 has a speaker built in to the front panel of the device to sound audible alarms when appropriate.

- The alarm icon at the bottom of the screen allows you to silence all high, medium, and low alarm(s).
- This button toggles between three states: On, Off, Pause

  PRECAUTION: It is not recommended to select Off to turn off the audible alarms.
- Pause will display a countdown 120 seconds before the alarm becomes active again. When the Responder 2000 is fully charged and ready to deliver a shock, the user cannot silence or turn down the beeping.

ADJUSTING HEART RATE ALARM LIMITS

1. Rotate Rotary Selector Knob and select Heart Rate Alarm

2. Rotate Rotary Selector Knob and Select Low Alarm Limit Range
   Available Low Alarm Settings: Off, 25-120 (in increments of 5)
   Default: 40

3. Press Rotary Selector Knob to confirm setting

4. Rotate Rotary Selector Knob and Select High Alarm Limit Range
   Available Settings: 40-300 (increments of 5), Off
   Default: 180

SETTING THE ECG SOURCE AND GAIN

1. To set the source for the ECG waveforms, rotate the Rotary Selector Knob to highlight the current ECG selection.

2. Press Rotary Selector knob to select setting.

3. Turn the Rotary Selector Knob again to increment the source selection. The options are:
   - ECG I, ECG II or ECG III
   - aVR
   - aVF
   - aVL
   - V
   - Paddles

4. Press the Rotary Selector Knob to confirm your selection.

5. To set the Gain for the displayed waveform, rotate the Rotary Selector knob to highlight the gain value.

NOTE: The gain in display does not affect the gain on the printout. The printout is always at 1x gain.

6. Rotate the Rotary Selector Knob to increment the Gain value
   Available options: 0.25x, 0.5x, 1x, 2x, and 4x.

7. Press the Rotary Selector Knob to confirm your choice. The waveform size will adjust accordingly.

SECTION 4: CONFIGURING THE RESPONDER 2000 SETTINGS

OVERVIEW

The Responder 2000 features a flexible configuration set-up. Menus with controls and options specific to each function of the Responder 2000 are easily accessible and configurable through the Menu Select and Rotary Selector Knob located on the front panel. Menus are used to adjust settings for defibrillation, pacing, channel display, alarms, system, date and time, and user settings.

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USER SETTINGS	95

SETTINGS MENU

The Settings Menu allows customization to the Responder 2000 settings, which means that they are retained in memory and are activated automatically when you power on the device.

The Settings Menu allows you to make adjustments to view the following settings.

The followings menu selections are available from the Settings menu.

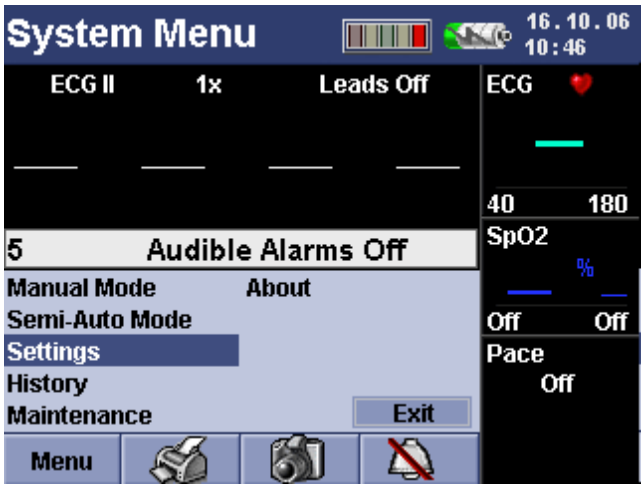
- Defibrillation Settings
- Pacing Settings
- Channel Settings
- Alarms/Sounds Settings
- Date/Time Settings
- User Settings Menu
- System Settings Menu

PRECAUTION: Do not enter settings menu while connected to the patient.

TO VIEW THE SETTINGS MENU

From the **Monitor** screen,

1. Rotate the Rotary Selector Knob to the **Menu**.
2. Push the Rotary Selector Knob to open the System Menu
3. Rotate the Rotary Selector Knob to **Settings**



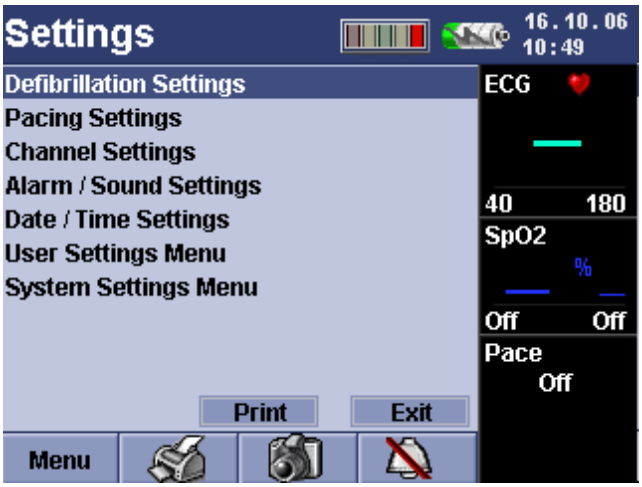
TO VIEW THE SETTINGS MENU (CONTINUED)

4. Push the Rotary Selector Knob
5. A password may be required to change the settings.

6. To enter the password, push the Rotary Selector Knob. It will highlight the first space. There is no default password. If a password needs to be reset, enter **VASCULAR**.

TO VIEW THE SETTINGS MENU (CONTINUED)

7. Push the Rotary Selector Knob and rotate the Rotary Selector Knob to scroll through the alphabet and numbers in this field.
8. Push the Rotary Selector Knob when the letter you want is displayed. Repeat this for each space until the password is complete.
9. When you are finished entering the password, turn the Rotary Selector Knob clockwise until the password box is highlighted. Push the Rotary Selector Knob.
10. Turn the Rotary Selector Knob to **Accept** and push the Rotary Selector Knob**.**
11. After successfully entering the password, the Setting menu will now appear.



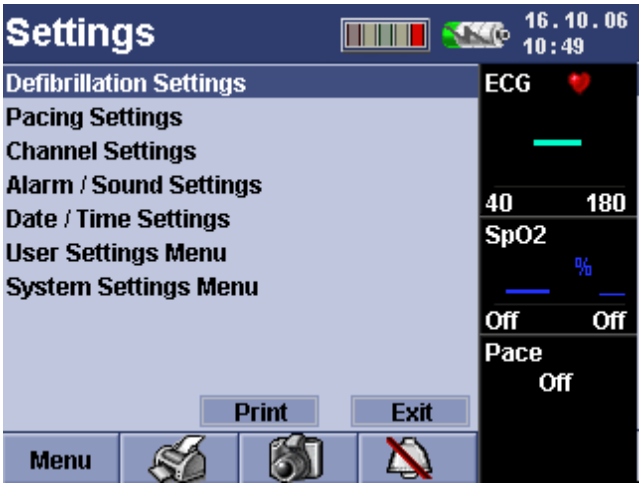
NOTE: To change the password, see TO CHANGE THE PASSWORD in this section of the manual.

NOTE: All changes to the settings of the Responder 2000 must be performed before connecting the Responder 2000 to the patient.

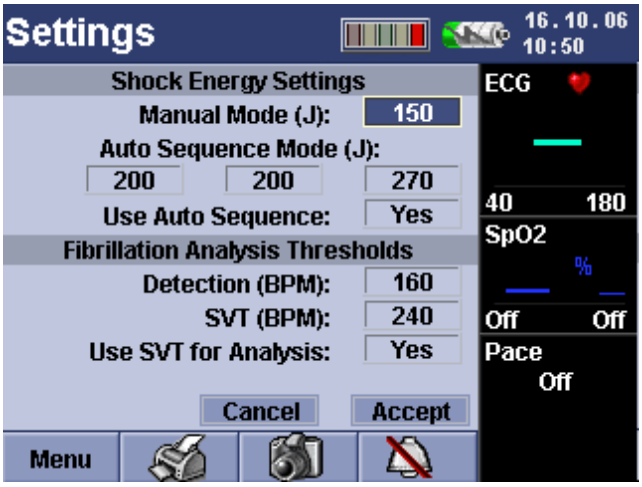
DEFIBRILLATION SETTINGS

The Responder 2000 Defibrillation Settings can be configured to the desired setting.

1. From the Settings menu, rotate the Rotary Selector Knob to **Defibrillation Settings.**



2. Push the Rotary Selector Knob to view **Defibrillation Settings**.



3. Turn the Rotary Selector Knob to highlight the desired setting.
4. Press the Rotary Selector Knob.
5. Turn the Rotary Selector Knob again to scroll through the settings and press to confirm the new value.
6. After selecting desired default settings, turn the Rotary Selector Knob to **Accept**.
7. Press the Rotary Selector Knob.

DEFAULT SHOCK ENERGY SETTINGS

The **Default Shock Energy Settings** menu allows default settings to be selected for **Manual Mode**, **Auto Sequence Mode** and **Use Auto Sequence**.

Manual Mode	Auto Sequence Mode	Use Auto Sequence Mode
Factory Default: 150 Joules	Factory Default: 200, 200, 270 Joules	Factory Default: Yes
Available Settings: 2, 3, 5, 7,10,15, 20, 30, 50, 70, 100, 150, 200, 270 Joules	Available Settings for first, second and third shock: 2, 3, 5, 7, 10, 15, 20, 30, 50, 70, 100, 150, 200, 270 Joules	Available Settings: Yes or No

NOTE: The maximum energy for spoons is 50 joules.

FIBRILLATION ANALYSIS THRESHOLDS

The **Fibrillation Analysis Thresholds** menu allows default settings to be selected for **Detection (BPM)**, **SVT (BPM),** and **Use SVT for analysis**.

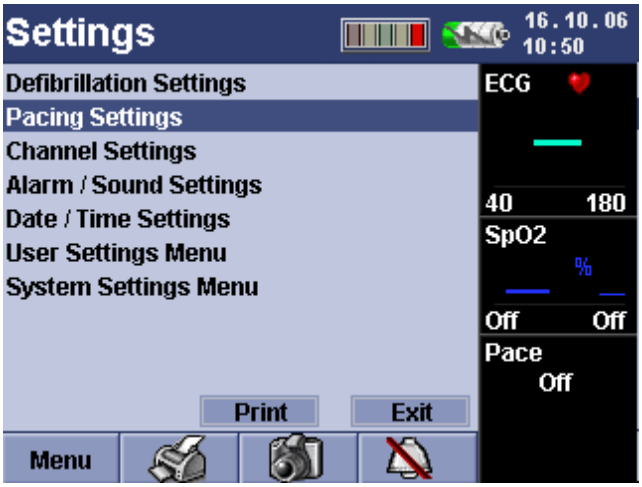
Detection (BPM)	SVT (BPM)	Use SVT for analysis
Factory Default: 160	Factory Default: 240	Factory Default: Yes
Available Settings: 120 through 240 in (increments of 5)	Available Settings: 120 through 240 (increments of 5)	Available Settings: Yes or No

PACING SETTINGS

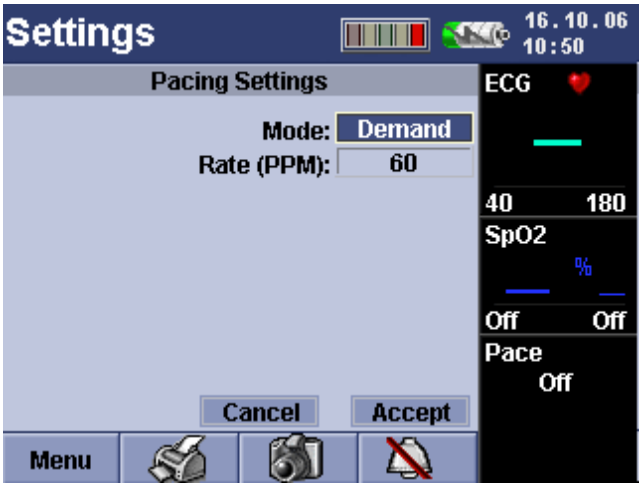
The Responder 2000 Pacing settings can be configured to the desired setting from the Settings or Pacing mode box on the startup menu. Pacing mode is turned off by default.

TO CHANGE PACING SETTINGS FROM SETTINGS MENU

1. From the Settings menu, rotate the Rotary Selector Knob to **Pacing Settings** and push Rotary Selector Knob to select.



2. Select Pacing Default Parameters – Mode and Rate (PPM) by rotating Rotary Selector Knob to each setting. Push to select setting, rotate to select option, and push to select desired default setting.



3. Rotate Rotary Selector Knob to Accept push to confirm settings.

TO CHANGE SETTINGS FROM STARTUP MENU

1. From the startup menu, use Rotary Selector Knob to move focus to Pacing mode box in the bottom right hand side of the menu.
2. Press the Rotary Selector knob to change the Pacing Settings.
3. After selecting the desired pacing mode, current, and rate settings, turn the selector knob to highlight the Pacing mode box and press the rotary knob to confirm the settings.
4. Use Rotary Selector Knob to move focus to Pacing Mode Edit box and press Rotary Selector knob to select it.

PACING DEFAULT PARAMETERS

Mode	Current	Rate (PPM)
Factory Default: Demand	Factory Default: 0 mA	Factory Default: 60
Available Settings: Demand, Fixed	Available Settings: 0 mA – 140mA	Available Settings: 30 - 180
	(increments of 5)	(increments of 5)

CHANNEL SETTINGS

The Responder 2000 Channel Settings can be configured to the desired setting.

1. From the Settings menu, rotate the Rotary Selector Knob to **Channel Settings.**

2. Push the Rotary Selector Knob to view **Channel Settings**.

3. Turn the Rotary Selector Knob to highlight the desired setting.
4. Press the Rotary Selector Knob.
5. Turn the Rotary Selector Knob again to scroll through the settings and press to confirm the new value.
6. After selecting desired default settings, turn the Rotary Selector Knob to Accept.
7. Press the Rotary Selector Knob.

CHANNEL 1

The Channel 1 menu allows default settings to be selected for Source and Gain.

Source	Auto-switch Source
Factory Default: ECG II	Factory Default: Off
Available Settings: ECG 1, ECG II, ECG III, aVR, aVF, aVL, V, Paddles	Available Settings: On, Off

Gain
Factory Default: 1x
Available Settings: .25x, 0.5x, 1x, 2x, 4x

CHANNEL 2

The Channel 2 menu allows default settings to be selected for Source and Gain.

Source	Gain
Factory Default: SpO_2 with Option, Otherwise Cascade	Factory Default: 1x
Available Settings: Cascade, SpO_2	Available Settings: .25x, 0.5x, 1x, 2x, 4x

FILTERS

The **Filters** menu allows default settings to be selected for **Line Filter (Hz)** and **Muscle Filter**.
Selection only valid for ECG channel, but not for pads/paddles channel.

Line Filter (Hz)	Muscle Filter
Factory Default: Off	Factory Default: On
Available Settings: Off, 50, 60	Available Settings: On, Off
	Always On, if pads/paddles selected.

ALARMS/SOUND SETTINGS

The Responder 2000 Alarm/Sound Settings can be configured to the desired setting.

1. From the Settings menu, rotate the Rotary Selector Knob to **Alarms/Sound Settings.**

2. Push the Rotary Selector Knob to view **Alarms/Sound Settings**.

3. Turn the Rotary Selector Knob to highlight the desired setting.
4. Press the Rotary Selector Knob.
5. Turn the Rotary Selector Knob again to scroll through the settings and press to confirm the new value.
6. After selecting desired default settings, turn the Rotary Selector Knob to Accept.
7. Press the Rotary Selector Knob.

AUDIO DEFAULTS

Audible Alarm	Volume	Pulse Beep
Factory Default: Off	Factory Default: Loud	Factory Default: Soft
Available Settings: On, Off	Available Settings: Soft, Medium, Loud	Available Settings: Off, Soft, Medium, Loud

PATIENT TRIGGERS

Low Heart Rate (BPM)	High Heart Rate (BPM)
Factory Default: 40	Factory Default: 180
Available Settings: Off, 25-120 (increments of 5)	Available Settings: 40-300, Off (increments of 5)

Low SpO_2 Sat (%)	High SpO_2 Sat (%)
Factory Default: Off	Factory Default: Off
Available Settings: Off, 81-98% (increments of 1)	Available Settings: 95-100%, Off (increments of 1)

DATE/TIME SETTINGS

The Responder 2000 time, date, and date format can be configured to the desired setting.

1. From the Settings menu, rotate the Rotary Selector Knob to **Date/Time Settings.**

2. Press the Rotary Selector Knob to select **Date/Time Settings**.
3. The Date/Time Settings screen will be displayed.

4. For each setting, rotate the Rotary Selector Knob clockwise and counterclockwise to select the desired value.
5. Push the Rotary Selector Knob to select desired setting.
6. To save the time, date, and date format settings, rotate Rotary Selector Knob to **Accept** and push.

TIME SETTINGS	DATE SETTINGS
Hour format: HH Hour Value: 00 through 23 Minute Format: MM Minute Value: 00 through 59 Time Format: AM/PM, 24 Hour Default Time Format: 24 Hour	Date format: DD Date Value: 1 through 31 Month Format: MM Month Value: 01 through 12 01 January — 04 April — 07 July — 10 October 02 February — 05 May — 08 August — 11 November 03 March — 06 June — 09 September — 12 December Year format: YY Year Value: 04 through 99 Date Format: Month/Day/Year, Year/Month/Day, Day.Month.Year Default Date Format: Day.Month.Year ***NOTE:*** The Responder 2000 does not automatically adjust the Date/Time for Daylight Savings.

USER SETTINGS MENU

The Responder 2000 User Settings Menu allows you to store the name of your institution in the device and create a new password.

1. From the Settings menu, rotate the Rotary Selector Knob to **User Settings Menu.**

2. Push the Rotary Selector Knob to view **User Settings Menu**.

3. Turn the Rotary Selector Knob to highlight the desired setting.
4. Press the Rotary Selector Knob.
5. Turn the Rotary Selector Knob to select Facility or Set Password.
6. Press the Rotary Selector Knob.
7. After setting up System Settings, Select Exit to go back to main screen, or Back then the Rotary Selector Knob to go back to the System Settings menu.

FACILITY

The Facility menu allows you to store the name of the institution in the device.

1. Push the Rotary Selector Knob to bring the cursor to the first space.
2. Push the Rotary Selector Knob again to select the letter, number, punctuation.
3. Turn the Rotary Selector Knob to scroll through the English only alphabet and numbers in this field.

4. Push the Rotary Selector Knob when the letter you want is displayed. Repeat this for each space until the name is complete.
5. When you are finished entering the desired name, turn the Rotary Selector Knob clockwise until the name box is highlighted. Push the Rotary Selector Knob.
6. Turn the Rotary Selector Knob to **Accept** and push the Rotary Selector Knob**.**

SET PASSWORD

The Responder 2000 Set Password Menu allows you create a unique password.

There is no default password.

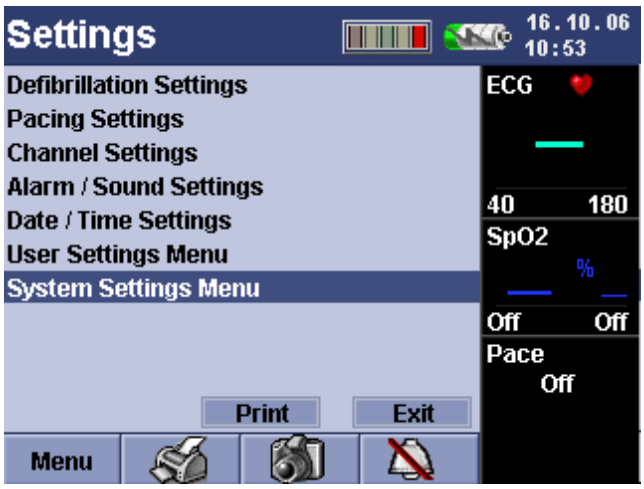
1. To open the Set Password menu, turn the Rotary Selector Knob to **Set Password** and press the Rotary Selector Knob.

2. Push the Rotary Selector Knob to bring the cursor to the first space.
3. Push the Rotary Selector Knob again to select the letter or number.
4. Turn the Rotary Selector Knob to scroll through the English only alphabet and numbers in this field.
5. Push the Rotary Selector Knob when the letter you want is displayed. Repeat this for each space until the name is complete.
6. When you are finished entering the desired password, turn the Rotary Selector Knob clockwise until the name box is highlighted. Push the Rotary Selector Knob.
7. Re-enter the New Password again.
8. Turn the Rotary Selector Knob to Accept and push the Rotary Selector Knob.
9. When you are finished re-entering the password, turn the Rotary Selector Knob clockwise until the name box is highlighted. Push the Rotary Selector Knob.
10. Turn the Rotary Selector Knob to Accept and push the Rotary Selector Knob.

SYSTEM SETTINGS MENU

The Responder 2000 System Settings menu allows you to configure display, printer, power-up settings as well as restoring Responder 2000 defaults.

1. From the Settings menu, rotate the Rotary Selector Knob to **System Settings Menu.**



2. Push the Rotary Selector Knob to view **System Settings Menu**.

3. Turn the Rotary Selector Knob to highlight the desired setting.
4. Press the Rotary Selector Knob.
5. Turn the Rotary Selector Knob to select **Display Settings**, **Printer Settings, Power-Up Settings**, or **Restore Defaults.**
6. Press the Rotary Selector Knob.
7. After setting up System Settings, Select **Exit** to enter **Monitor Mode** or **Back** to **back to System Settings menu**.

DISPLAY SETTINGS

The Responder 2000 Display Settings menu allows you to configure the backlight of the graphics display.

1. From the Settings menu, rotate the Rotary Selector Knob to **Display Settings**

2. Push the Rotary Selector Knob to view **Display Settings** settings.

DISPLAY SETTINGS (CONTINUED)

3. Turn the Rotary Selector Knob to select the desired value.
   Default Value: Bright
   Available Settings:Dim, Medium, Bright
4. After selecting desired setting, push the Rotary Selector Knob.
5. Turn the Rotary Selector Knob to **Accept**.
6. Press the Rotary Selector Knob.

PRINTER SETTINGS

The Responder 2000 Printer Settings menu allows you to configure printer options.

1. From the Settings menu, rotate the Rotary Selector Knob to **Printer Settings**

2. Push the Rotary Selector Knob to view **Printer Settings** settings.

3. Turn the Rotary Selector Knob to highlight the desired setting.
4. Press the Rotary Selector Knob.
5. Turn the Rotary Selector Knob to select the desired value.
6. After selecting desired default settings, turn the Rotary Selector Knob to Accept.
7. Press the Rotary Selector Knob.

User Intitiated Print Option Duration	Event Initiated Print Option
Factory Default: 20 seconds	Factory Default: Shock 20 Seconds
Available Settings: 20 seconds, Continuous	Available Settings: Shock 20 Seconds, Auto 20 Seconds, Auto Continuous, Off

POWER-UP SETTINGS

The Responder 2000 Power-up Setting's menu allows you to configure and set the default mode.

1. From the Settings menu, rotate the Rotary Selector Knob to **Power-Up Settings**

2. Push the Rotary Selector Knob to view **Power-Up Settings**.

3. Turn the Rotary Selector Knob to highlight the desired setting.
4. Press the Rotary Selector Knob.
5. Turn the Rotary Selector Knob to Accept and press the Rotary Selector Knob to accept the desired value.

POWER-UP MODE DEFAULT

Power up Mode Default: Manual Mode

Available Settings: Manual Mode, Semi-Auto Mode, Monitor Mode

1. Press the Rotary Selector Knob.
2. After selecting desired default settings, turn the Rotary Selector Knob to Accept.
3. Press the Rotary Selector Knob.

RESTORE DEFAULTS

The Responder 2000 Restore Defaults menu allows you to restore all settings to factory recommended defaults.

1. From the Settings menu, rotate the Rotary Selector Knob to **Restore Defaults Settings**

2. Push the Rotary Selector Knob to view **Restore Defaults Settings** settings.
3. Turn the Rotary Selector Knob to **Accept**.
4. Press the Rotary Selector Knob.
5. The Responder 2000 default settings will be restored.

DEFAULT SETTINGS

When the Restore Defaults option is selected, the settings will be changed to the factory defaults as specified in the table below.

NOTE: Change power-up default in Menu, do not change on display.

Item	***Factory Default***
Display: Channel 1 Source	ECG II
Display: Channel 1 Gain	1x
Display: Channel 2 Source	SpO_2
Display: Channel 2 Gain	1x
ECG Info Box: Low Alarm	40
ECG Info Box: High Alarm	180
SpO2 Info Box: Low Alarm	Off
SpO2 Info Box: High Alarm	Off
Pacing Info Box: On/Off/Pause	Off
Alarm Button:	Off
Menu->Settings->Defibrillation->Manual Mode	150J
Menu->Settings->Defibrillation->Use Auto Sequence	Yes
Menu->Settings->Defibrillation->Auto Sequence Energy #1	200
Menu->Settings->Defibrillation->Auto Sequence Energy #2	200
Menu->Settings->Defibrillation->Auto Sequence Energy #3	270
Menu->Settings->Defibrillation->Detection	160
Menu->Settings->Defibrillation->SVT	240
Menu->Settings->Defibrillation->Use SVT For Analysis	Yes
Menu->Settings->Pacing->Mode	Demand
Menu->Settings->Pacing->Rate	60
Menu->Settings->Channel Display->Channel 1 Source	ECG II
Menu->Settings->Channel Display->Channel 1 Gain	1x
Menu->Settings->Channel Display->Channel 2 Source	SpO2
Menu->Settings->Channel Display->Channel 2 Gain	1x
Menu->Settings->Channel Display->Line Filter	Off
Menu->Settings->Channel Display->Muscle Filter	On
Menu->Settings->Alarms and Sound->Audible Alarm	Off
Menu->Settings->Alarms and Sound->Volume	Loud
Menu->Settings->Alarms and Sound->Pulse Beep	Soft
Menu->Settings->Alarms and Sound->Low Heart Rate	40
Menu->Settings->Alarms and Sound->High Heart Rate	180
Menu->Settings->Alarms and Sound->Low SpO2 Sat	Off
Menu->Settings->Alarms and Sound->High SpO2 Sat	Off
Menu->Settings->System Settings->Display Settings->Level	Bright
Menu->Settings->System Settings->Printer Settings->Duration	20 Sec
Menu->Settings->System Settings->Printer Settings->Events	Shock 20 Seconds
Menu->Settings->System Settings->Power-Up Settings->Mode	Manual Mode
Menu->Settings->Date and Time->Hour	N/A
Menu->Settings->Date and Time->Minute	N/A
Menu->Settings->Date and Time->Format	24 Hour
Menu->Settings->Date and Time->Day	N/A
Menu->Settings->Date and Time->Month	N/A
Menu->Settings->Date and Time->Year	N/A
Menu->Settings->Date and Time->Format	Day.Month.Year
Menu->Settings->User Settings->Facility Name	<blank>
Menu->Settings->User Settings->Set Password	<blank>

SECTION 5: MAINTENANCE & SERVICE

OVERVIEW

Proper maintenance of the Responder 2000 is very simple, yet it is an important factor in its reliability. This section describes the maintenance and service required for the Responder 2000 and its accessories.

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PADDLE AND INTERNAL PADDLE CLEANING INSTRUCTIONS	111
INTERNAL PADDLE STERILIZATION INSTRUCTIONS	111
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RECOMMENDED MAINTENANCE AND CARE

WARNING: Failure on the part of all responsible individuals, hospitals, or institutions, employing the use of Responder 2000, to implement the recommended maintenance schedule may cause equipment failure and possible health hazards. The manufacturer does not, in any manner, assumes the responsibility for performing the recommended maintenance schedule. The sole responsibility rests with the individuals, hospitals, or institutions utilizing the Responder 2000.

To ensure the Responder 2000 is always functional when required, the following maintenance must be performed:

- Performing a Visual Inspection
- Cleaning the Responder 2000 and its accessories
- Calibrating the battery fuel gauge
- Daily Maintenance per Defibrillator Checklist in this section

- It is recommended that the Responder 2000 be plugged into a power source at all times. This will ensure your battery is fully charged and the Responder 2000 is ready to use. Battery charging /charge maintenance will occur as long as the Responder 2000 is plugged into a properly functioning electrical outlet source.

- It is important that the Responder 2000 is stored at the operating temperature range if it is expected to be used. Optimal battery life will be obtained if stored and operated at room temperature. See Section 7 for Temperature Specifications.

- The Responder 2000 requires no calibration except for periodic calibration of the fuel gauge in the rechargeable battery.

- Discard all disposable pads or electrodes immediately after use.

VISUAL INSPECTION

The Responder 2000 and its accessories should be carefully inspected prior to installation, daily, and each time the equipment is serviced.

- Carefully inspect the equipment for physical damage
- Inspect all external connections for loose connectors or frayed cables.
- Inspect the graphics display for marks, scratches, or other damage.
- Verify that the Safety label on back of the Responder 2000 is clearly legible

INSTRUCTION	INSPECT FOR	RECOMMENDED REMEDY
Examine the case connectors and accessories	Foreign substances	Clean the Responder 2000 and its accessories as described.
	Damage or cracks	Replace if damaged or cracked
	Cables or Connector Pins bent or discolored	Replace if damaged or cracked
With unit plugged into an active AC outlet, turn power on	Battery Indicator is showing battery low	Plug Responder 2000 in using power cord to charge battery.
Examine accessory cables	Foreign substances	Clean the cables as described in the Section 5
	Broken parts, cracks, damage, or extreme wear, broken or bent connectors and pins, after bending and flexing the cable	Replace cable if any abnormalities are found.
Examine disposable accessories	Expired ECG or Responder 2000 pads	Replace any products approaching or past their expiration dates.

WARNING: After the visual inspection, if the Responder 2000 and/or its accessories are damaged please contact Customer Service. The Responder 2000 will need to be repaired. The accessories should be disposed of appropriately and replacement parts shall be ordered.

CLEANING RESPONDER 2000 AND ACCESSORIES

It is recommended that the Responder 2000 and its accessories to be inspected after each use according to the Defibrillator Checklist in this manual and cleaned when appropriate.

Listed below are recommendations for cleaning the Responder 2000 and its accessories.

RECOMMENDED CLEANING PRODUCTS

The following cleaning products may be used to clean the exterior surfaces of the Responder 2000 as well as the batteries:

- 3% Hydrogen Peroxide
- 100% Ethyl Alcohol
- 91% Isopropyl Alcohol
- Mild soap and water

- Do not use abrasive cleaners or strong solvents such as acetone or acetone-based cleaners.
- Do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may occur
- Do not clean electrical contacts or connectors with bleach.

CLEANING INSTRUCTIONS

1. Before cleaning the Responder 2000, turn the device off, disconnect the power cord, and remove battery.

2. Before cleaning, also remove all adherent soil (tissue, fluids, etc.) and wipe thoroughly with a cloth dampened with water before applying the cleaning solution.

3. When cleaning, do not immerse.

4. Wring any excess moisture from the cloth before cleaning.

5. Avoid pouring fluids on the device, and do not allow fluids to penetrate the exterior surfaces of the device.

6. To prevent scratching the display, the use of a soft cloth is recommended.

PRECAUTION: To prevent damage to equipment, do not clean any part of the Responder 2000 or its accessories (with the exception of internal paddles/spoons) with phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not steam, autoclave, or gas-sterilize the Responder 2000 or accessories.

WARNING: Cleaning liquids: DO NOT submerge the device in liquids or pour cleaning liquids over, into or onto the device.

PRINTER CLEANING INSTRUCTIONS

To clean the Responder 2000 Printer:

1. Pull the printer door latch to open the door.
2. Remove the roll of paper.
3. Clean the print head surface with a cotton swab dipped in isopropyl alcohol.
4. Replace the roll of paper

PADDLE AND INTERNAL PADDLE CLEANING INSTRUCTIONS

Before cleaning the paddles, disconnect them from the Responder 2000. The paddles, paddle cradles, and internal paddles can be cleaned and disinfected by wiping down with a gauze pad moistened in a cleaning solution. Use the cleaning products recommended for cleaning of the Responder 2000 unit. Before applying the paddles again, check that they have thoroughly dried.

INTERNAL PADDLE STERILIZATION INSTRUCTIONS

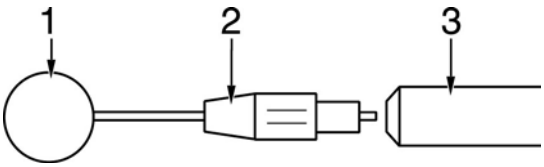
Internal paddles sterilization instructions are listed below.

PRECAUTION: Electrode Damage — Do not sterilize the electrodes for internal defibrillation (spoons) with hot air. Cable Damage — Disconnect the cable from the electrodes before sterilization.

The electrodes and connecting cables should be sterilized by the low-temperature plasma sterilization method. Alternative methods are ETO sterilization, water vapor (134 °C) or ionizing radiation. Ensure that internal defibrillation electrodes are sterilized before each use.

INSERTING THE SPOON ELECTRODE

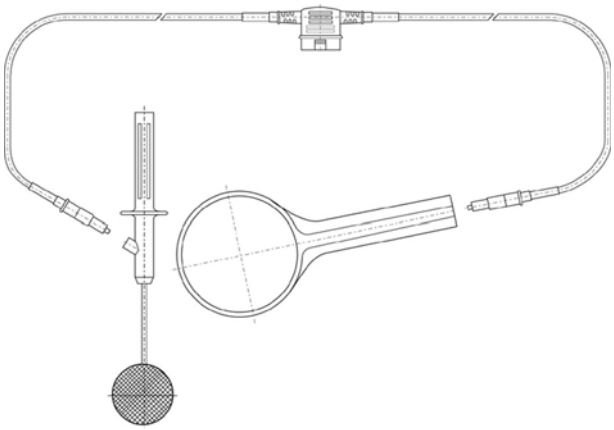
- Screw the counter nut **2** onto the electrode as far as it will go.
- Screw the contact paddle **1** into the handle as far as it will go, then bring it into the appropriate position.
- Now fix the contact paddle by screwing the counter nut **2** tight against the handle **3**.



NOTE: Having loosened the counter nut 2, you can easily alter the position of the contact paddle.

EXTERNAL COUNTER ELECTRODE FOR INTERNAL DEFIBRILLATION

- Disconnect the electrode from its lead before cleaning or sterilizing it.
- Clean the electrode by rubbing it down with a cloth moistened with soap water. Use a disinfectant for disinfection. Do not immerse the electrode in the liquid.
- Low-temperature plasma sterilization is the recommended sterilization method. Alternative methods are ETO sterilization or ionizing radiation. (Please note: Frequent ETO sterilization reduces the life expectancy of the plastic material!) Do not autoclave the electrodes.



CARING FOR RECHARGEABLE BATTERIES

CALIBRATING THE BATTERY FUEL GAUGE

Time, repeated partial charges and discharges, and battery aging will lead to inaccuracy of the battery fuel gauge. This is corrected by performing a battery calibration cycle. To maintain useful battery life, it is recommended to calibrate the rechargeable battery:

- Once every two months
- When the run time of the battery becomes noticeably shorter
- When the predicted run times become noticeably inaccurate

To calibrate a Responder 2000 battery, see Section 2.

RECYCLING THE BATTERIES

When the battery no longer holds a charge, it should be replaced. This condition may occur after 2.5 years or 300 charge/discharge cycles. The batteries are recyclable. Remove the old battery from the Responder 2000 and follow your local recycling guidelines.

DEFIBRILLATOR CHECKLIST

Daily maintenance activities involve verifying output energy, testing key controls and functions, making sure all necessary accessory items are present, assuring date coded items are within their effective terms, checking for obvious damage (worn or frayed cables, case cracks, etc.), and confirming/testing battery performance.

Daily maintenance should always be performed by qualified personnel.

The following daily checklist is recommended to be utilized when checking the defibrillator:

INSTRUCTIONS	OK	CORRECTIVE ACTION
1. Inspect Responder 2000 housing for:		
a) Ensure that it is clean, free from spills, clear of objects, housing intact, and there are no signs of visible damage.		Clean the device if necessary
2. Inspect Supplies:		
a) Check that the following supplies are present and within the expiration date:		
Monitoring electrodes		Replace if expired or used
Gel		Replace if expired
Defibrillation pads		Replace if expired or used
b) Check for adequate paper supply		Replace if empty or low
Ensure that a spare charged battery is available		Replace spare battery if missing
3. Inspect Battery For:		
a) Ensure that it is clean, free from spills, and there are no signs of visible damage.		Clean the battery if necessary
b) Damage or cracks; broken, loose, or worn battery pins		Replace battery if necessary
c) Damaged or leaking battery		Replace battery if damaged or leaking
d) Verify battery is charged.		Plug device into electrical outlet if battery is not fully charged
e) Verify that the battery latch is working properly		If latch is not working properly, Contact Customer Service
4. Inspect Paddles For:		
a) Verify paddles are not pitted or damaged		Replace paddles if pitted or damaged
b) Verify that they release from the housing easily		If this is not the case, please contact Customer Service.
c) If internal paddles are included, verify that they are available in a sterile package.		Replace if opened
d) Remove the adult surface plate from the paddles. Verify pediatric paddles are clean, not pitted or damaged.		Replace paddles if necessary
e) Verify the paddle holder latches are working properly.		If latches are not working properly, Contact Customer Service.

5.	Inspect Cables/Connectors		
a)	Inspect for cracks, broken wires, or other signs of damage.		Replace if cracked or damaged
b)	Verify that connectors are engaged securely		If this is not the case, please contact Customer Service.
6.	Inspect Indicators and Display:		
a)	Turn Machine on		
	(Green) Power button light illuminated		If this is not the case, please contact Customer Service.
	(Red) Service LED stays illuminated		Take the device out of use and call Customer Service.
	(Red) Service LED turns on Briefly		No Action
	(Yellow) Charging button light illuminates		If that's not the case, please contact Customer Service.
b)	Verify AC Power, Service Required, and Battery Charging LEDs turn on momentarily during power on.		If this is not the case, please contact Customer Service.
c)	During power on, verify a brief audible tone is output.		If this is not the case, please contact Customer Service.
d)	Verify Charge button backlight is momentarily turned on during power on.		If this is not the case, please contact Customer Service.
e)	Verify Shock button backlight is momentarily turned on during power on.		If this is not the case, please contact Customer Service.
f)	Press Manual button. Verify Manual Mode is exited. Press Manual button again and verify Manual Mode is entered.		If this is not the case, please contact Customer Service.
g)	Verify Power cable connected to Responder 2000		No Action
h)	Verify AC Power LED is turned on.		If this is not the case, please contact Customer Service.
i)	Verify Display is working correctly and no error messages are indicated.		If display is working incorrectly, take the device out of use. Please contact Customer Service.
j)	Place battery in unit and connect AC power. A green and a yellow LED shall be turned on the front panel, indicating AC is connected and battery is charging.		If this is not the case, please contact Customer Service.
k)	Turn Machine off		No Action

7.	Defibrillator Testing: A discharge test can be triggered to check the defibrillator discharge circuit. For this test the stored energy is discharged into the Responder 2000 via two contacts in the paddle cradle. ***WARNING:*** Equipment Damage Do not trigger more than five (5) consecutive test discharges (or internal safety discharges) within thirty (30) minutes.		
	a) Unplug power cord from Responder 2000 to allow battery powered operation		No Action
	b) Turn machine on		No Action
	Check battery state of charge		Unable to complete testing; Plug Responder 2000 into electrical outlet to charge battery and resume when fully charged.
	c) Perform Defibrillator Test		No Action
	Place paddles securely in the paddle cradles.		No Action
	Set the Responder 2000 energy to 270 joules. (See Section 4 for Configuring the Responder 2000.)		No Action
	Press the Charge button on the paddle to charge the Responder 2000		No Action
	When the selected energy has been reached, the Responder 2000 will output an audible alarm and display “Stand clear, press shock button” on the graphics display.		No Action
	Simultaneously press and hold the Shock buttons on both of the paddles.		No Action
	After defibrillation, the energy actually delivered into a 50-ohm resistance is displayed for the ten (10) seconds in place of the stored energy.		No Action
	Verify the delivered energy is not more than ±15% or ±4 joules (whichever is greater) from the selected value.		If the Responder 2000 is unable to charge to the selected energy so the selected energy or the stored energy differs, contact Customer Service.
	If thirty (30) seconds has passed without initiating a discharge, the device is disarmed. In this case the delivered energy is 0.		No Action
	d) Turn off the Responder 2000		No Action

8. Monitor Testing The performance of the monitor can be tested with the 2025269-003 Simulator.		
a) Make sure the battery is at least partially charged. Power the Responder 2000 from the battery only, i.e. disconnect AC power input to the device.		If the battery is not partially charged, wait and partially charge the battery.
b) Connect the ECG leads of the Responder 2000 to the simulator. Turn on the simulator. Select a normal sinus rhythm on the simulator. Make sure you are able to select all leads, and that the ECG signal is present, and is not distorted or noisy. Make sure there are no false pace pulse detections.		If the Responder 2000 is unable to turn on, or unable to select all leads, or the ECG signal is not present, or is distorted or noisy, contact Customer Service.
c) Turn the power to the Responder 2000 off. Remove the battery. Power the Responder 2000 from AC input only.		No Action
d) Connect the pads cable from the Responder 2000 to the simulator. Turn on the simulator. Select a normal sinus rhythm on the simulator. Make sure the ECG signal is present, and is not distorted or noisy. Make sure there are no false pace pulse detections.		If the Responder 2000 is unable to turn on, or if the ECG signal is not present, or is distorted or noisy, contact Customer Service.
9. SpO_2 Testing (if Responder 2000 has this option)		
Connect desired SpO_2 cable and connector combination to Responder 2000 and apply sensor to a test person.		No Action
Verify SpO_2 is plausible		If SpO_2 is displayed not plausible, please contact Customer Service.
10. Pacing The performance of the pacemaker can be tested with the 2025269-003 Simulator.		
Connect the pads cable from the Responder 2000 to the simulator. Turn on the simulator and the Responder 2000. Turn on the pacer and select pacer current > 60 mA. Verify pacer pulse LED at the simulator is flashing in the rhythm of the pace pulses.		If this is not the case, please contact Customer Service.

11. Paper Supply		
a) Verify that the paper used is manufactured or recommended by GE Medical Systems Information Technologies.		If this is not the case, replace it by paper manufactured or recommended by GE Medical Systems Information Technologies.
b) Confirm paper advances when Print is pressed		If this is not the case, please contact Customer Service.
c) Select Print from main menu. Verify contents printed correctly.		If Responder 2000 contents are printed incorrectly, please contact Customer Service.
12. Reconnect Responder 2000 to electrical outlet. It is now ready for use.		

AUTHORIZED REPAIR SERVICE

The Responder 2000 has no user-serviceable internal components. Try to resolve any maintenance issues with the Responder 2000 by using the Troubleshooting Table presented in this chapter. If you are unable to resolve the problem, contact Customer Service.

WARNING: Shock Hazard
Do not disassemble the Responder 2000! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to authorized service personnel.

NOTE: The warranty will be void upon unauthorized disassembly or service of the Responder 2000.

SECTION 6: SPECIFICATIONS & SAFETY

OVERVIEW

This section presents the specifications and safety standards of the Responder 2000.

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SPECIFICATIONS

DISPLAY	
Size: Type:	115.2mm X 86.4mm Transmissive Color TFT LCD
Resolution:	320 X 240 pixels
Number of waveform channels:	2
DEFIBRILLATOR	
Waveform:	Biphasic truncated exponential
Charge Time:	7 seconds nominal
Delivery Method:	Via pads, paddles or spoons
Paddles and Pads Energy Selections (50Ω load):	2, 3, 5, 7, 10, 15, 20, 30, 50, 70, 100, 150, 200, 270
Internal Paddle Energy Selections (50Ω load):	2, 3, 5, 7, 10, 15, 20, 30, 50
Energy Accuracy:	± 15% onto a 50Ω load or ± 3 Joules, whichever is greater
NON-INVASIVE PACING	
Output Waveform:	Rectilinear, constant current
Delivery Method	Via Pads
Pulse Width:	40 milliseconds ±4mS
Pacing Modes:	Demand or Asynchronous (Fixed Rate)
Pacing Rate:	Operator adjustable: 30 to 180 ppm, ± 5%
Pacing Current:	0mA to 140mA
SPO_2	
Display	Plethysmogram, digital value of percent saturation, and upper and lower alarm limits.
Display Update Period	8 seconds or less
Saturation Range	0 to 100%, in 1% increments
Low Saturation Alarm	Off, 81-98% in 1% increments
High Saturation Alarm	Off, 95-100% in 1% increments
Pulse Rate Range	20 to 255 BPM, in 1 BPM increments
Audible Alarm Delay	10 seconds or less
Visual Alarm Delay	2 seconds or less
Pulse Rate Accuracy	30 to 250 bpm: ± 2 digits or ± 2%, whichever is greater (without motion) 30 to 250 bpm: ± 3 digits (during low perfusion)
Saturation Accuracy	+/- 2 digits from 70% SpO2 to 100% SpO2 with D-O probes, except +/- 3 digits for D-O Ear Probe. OEM board accuracy +/-3 digits from 70%

ECG MONITORING	
Detection Lead:	Through either 3-lead and 5-lead patient cable, pads, or paddles
Lead Selection:	3-Lead Cable: (I, II, III) and 5-Lead (I, II, III, aVL,aVR, aVF, and V), PADS: (Modified Lead II)
Heart Rate Range:	25 to 300 bpm
Display Frequency Response (ECG Leads):	0.5 to 100 Hz (± 10 %)
Display Frequency Response (paddles):	3 Hz to 33 Hz (± 10 %); (-3db)
ECG Effective Sampling Rate:	1000 samples per second (ECG Leads), 128 samples per second (paddles)
Post Defibrillation Recovery:	8 seconds
Low Heart Rate Alarms:	Off, 25-120 bpm
High Heart Rate Alarms:	Off, 40-300 bpm
ECG Leads and paddles leakage current	Less than 10uA in normal; Less than 50uA in single fault condition
Dynamic Range: Input ECG signal amplitude:	± 5mV
Dynamic Range: DC Offset voltage:	± 500 mV ECG from ECG cable; ± 1000 mV (ECG from pads, paddles and spoons
Asystole Threshold	0.2mV (±0.1mV)
RECHARGEABLE BATTERY	
Battery Voltage:	11.1 V Nominal
Chemistry:	Lithium-ion
Compatibility:	Compatible with Responder 2000
Battery Capacity:	50 shocks, or 240 minutes monitoring time, or 72 minutes monitoring time with pacing
Battery Charge Time:	8 hours in Responder 2000, 4 hours in external charger, 20 hours for calibration cycle in external charger
Battery Standby:	6 months
Battery Life:	2.5 years or 300 Battery charge-discharge cycles, whichever comes first
Battery Weight:	1 lb. 3 oz; .54 kg
AC POWER SUPPLY	
Universal input:	100V to 240V~
	50Hz-60Hz
	200VA
PRINTER	
Speed	25 mm/s feed rate
Paper Size	60 mm paper width

PHYSICAL DIMENSIONS

Height: 10.8 inches/27.4 cm
Width: 11.7 inches/29.7 cm
Depth: 7.4 inches/18.8 cm

Weight: Less than 10lbs/4.5kg, excluding battery, paddles, and a full roll of paper.

ENVIRONMENTAL REQUIREMENTS

OPERATING CONDITIONS

Temperature: 0°C to 50°C (32 °F to 122°F)

Humidity: 10% to 95% RH, non-condensing

Air Pressure altitude: -500 ft (103kPa) to 15000 ft (57kPa)

STORAGE AND SHIPPING CONDITIONS

Temperature (Responder 2000): -20°C to 60°C (-4°F to 140°F)
Temperature (Pads): -12°C to 43°C (10°F to 110°F) for 2 years.

NOTE: Do not exceed 38°C (100°F) for periods greater than 6 months in duration. Always store the pads in their pouch to maintain freshness. Do not use if gel has dried out.

Humidity: 10% - 95% RH, non-condensing

Air Pressure altitude: -500 ft (103kPa) to 15000 ft (57kPa)

WARNING: Electrode performance may be adversely affected by pre-attaching and storing with defibrillator cable or exposure to air for long periods of time. These electrodes are not recommended for electrosurgery.

PRECAUTION: Environment of use
Responder 2000 is designed for indoor use. Operator must confirm that the environment of use meets the required operating environmental specifications before using.

PRECAUTION: Cold Environments
If the Responder 2000 is stored in an environment with a temperature below the operating temperature, the unit should be allowed to warm up to the needed operating temperature before using.

RHYTHMx® ECG ANALYSIS ALGORITHM

The RHYTHMx® ECG analysis algorithm provides superior ECG detection capabilities. The features available with the Responder 2000 include the following:

- Detection Rate
- Asystole Threshold
- Noise Detection
- Non-Committed Shock
- Synchronized Shock
- SVT Discriminators
- Supraventricular Tachycardia (SVT) Rate
- Continuous Monitoring

The Responder 2000 rejects all T-waves that are 1 millivolt or less in the conditions specified in ANSI/AAMI EC 13 section 4.1.2.1c.

The Responder 2000 will alarm tachycardia in the conditions specified in ANSI/AAMI EC 13 section 4.1.2.1 g) in less than 10 seconds.

For the alternating ECG complexes specified in ANSI/AAMI EC 13 figure 3, the Responder 2000 will indicate the following heart rates:

Figure 3a 40 bpm
Figure 3b 52 bpm
Figure 3c 59 bpm
Figure 3d 122 bpm

(Refer to the ANSI/AAMI EC 13 for the figures.)

The following sections describe specific Rhythmx® information.

DETECTION RATE

All ventricular fibrillation (VF) and ventricular tachycardia (VT) rhythms at or above this rate will be classified as shockable. All rhythms below this rate will be classified as non-shockable. This rate is configurable between 120 bpm (beats per minute) and 240 bpm. The default Detection Rate for the Responder 2000 is 160 bpm.

FINE VF

Fine VF is classified by the signal amplitude less than 0.2 mV peak-to-peak for eight (8) consecutive seconds, preceded by a shockable arrhythmia or the peak-to-peak amplitude less than 0.9 mV, the amplitude distribution indicator is less than amplitude distribution threshold, the derivative probability density function is satisfied, the RR interval index is not regular, and it is preceded by a shockable rhythm. Fine VF is a shockable arrhythmia.

ASYSTOLE

The signal amplitude is less than 0.2 mV peak-to-peak for 8 consecutive seconds and is not preceded by a shockable rhythm; the rhythm will be classified as Asystole. Asystole is not shockable.

NOISE DETECTION

The Responder 2000 will detect noise artifact in the ECG. Noise could be introduced by excessive moving of the patient or electronic noise from external sources like cellular and radiotelephones.

NON-COMMITTED SHOCK

After the Responder 2000 advises a shock, it continues to monitor the patient ECG rhythm. If the patient's rhythm changes to a non-shockable rhythm before the shock button is pressed, the shock will be cancelled.

SYNC MODE

The Responder 2000 is designed to deliver synchronized shock-on the R-wave for Sync Shock. The Responder 2000 will automatically attempt to synchronize a shock to the R-wave. If delivery cannot be synchronized within two seconds it will not deliver the shock. It is recommended to select/adjust to a lead with an unipolar R wave of about 1 mV peak amplitude for safe and reliable synchronization.

IEC 60601-2-4 (2002) and ANSI/AAMI DF 80 (2003), clause 104c states that the maximum delay from the “peak of the QRS” to the peak of the defibrillator output waveform shall be 60ms. Verification testing has shown that the Responder 2000 meets this requirement of the standards.

Some ECG leads may exhibit a bipolar QRS waveform complex, and in these cases, the RHYTHMx software in the Responder 2000 will pick the highest peak of the QRS complex for synchronization. The peak of the defibrillator output will occur in less than 60ms from this peak, and therefore the Responder 2000 meets the synchronization requirement of the standards.

In the case of these leads, certain defibrillator testers may use a different part of the QRS complex (for example the first, smaller peak) to measure synchronization time of defibrillation. This may give a measurement result that exceeds 60ms. Investigation has shown that the Responder 2000 does synchronize appropriately from the peak of the QRS complex, and meets the requirement of the standards in cases where a particular defibrillator tester does not measure the defibrillation delay from the peak of the QRS complex.

SVT (Supraventricular Tachycardia) DISCRIMINATORS

The Responder 2000 is supplied with the SVT Discriminator enabled and the default setting is 240 bpm. SVT Discriminators are sophisticated filters that analyze the morphology of the ECG waveforms and distinguish VF/VT from SVT and Normal Sinus Rhythms (NSR). The SVT Discriminator will only be applied to rhythms that fall between the Detection Rate and the SVT Rate.

SVT RATE

All rhythms with rates between the Detection Rate and SVT Rate will be screened through a number of SVT Discriminators to classify them into VF/VT or SVT. Rhythms classified as SVT between the two set rates are not shockable. All rhythms above the rates will be classified as shockable. The SVT Rate must be greater than the Detection Rate and is selectable between 125 and 240 bpm. The default SVT rate is 240.

CONTINUOUS MONITORING FOR SHOCKABLE RHYTHM

The Responder 2000 can monitor the ECG rhythms continuously.

PACEMAKER PULSE INFORMATION

Pacemaker pulses without overshoot, in all of the conditions specified in ANSI/AAMI EC13 section 4.1.4.1, in the range of 20mV to 700mV and 0.1 milliseconds to 2 milliseconds wide, will be rejected by the Responder 2000.

Pacemaker pulses with overshoot, in all the conditions specified in ANSI/AAMI EC 13 section 4.1.4.2, in the range of 20mV to 700MmV and 0.1 milliseconds to 2 milliseconds wide, will be rejected by the Responder 2000.

The pacer pulse detector will not respond to the waveform of ANSI/AAMI figure 5d, since this waveform is below the threshold of the Responder 2000 pacer pulse detector. The minimum typical slew rate in V/s RTI that will trip the pacer detector is 6.2 V/s for the 3 and 5 lead ECG. The minimum typical slew rate in V/s RTI that will trip the pacer detector is 9.8 V/s for paddles.

STAR® BIPHASIC DEFIBRILLATION WAVEFORM

The waveform generated by the Responder 2000 is a BIPHASIC TRUNCATED EXPONENTIAL waveform that is compliant with ANSI/AAMI DF80.

STAR® Biphasic Waveform – 270J into Pads or paddles

Table A - 270J Waveform into Different Resistive Loads (Typical Values)

Patient's Impedance (Ohms)	Phase 1 Delivered Start Volts	Phase 1 Delivered End Volts	Phase 1 Duration (ms)	Phase 2 Delivered Start Volts	Phase 2 Delivered End Volts	Phase 2 Duration (ms)	Total Energy Delivered (J)
25	1692V	990V	3.25 ms	990V	342V	3.2ms	281J
50	1860V	1234V	4.50 ms	1234V	684V	3.2ms	270J
75	1923V	1338V	5.75ms	1338V	887V	3.2ms	254J
100	1957V	1394V	7.00 ms	1394V	1015V	3.2ms	241J
125	1977V	1429V	8.25ms	1429V	1103V	3.2ms	231J
150	1991V	1453V	9.50 ms	1453V	1166V	3.2ms	223J
175	2002V	1469V	10.75ms	1469V	1214V	3.2ms	217J
180	2003V	1472V	11.00ms	1472V	1222V	3.2ms	216J
200	2009V	1520V	11.00ms	1520V	1283V	3.2ms	202J

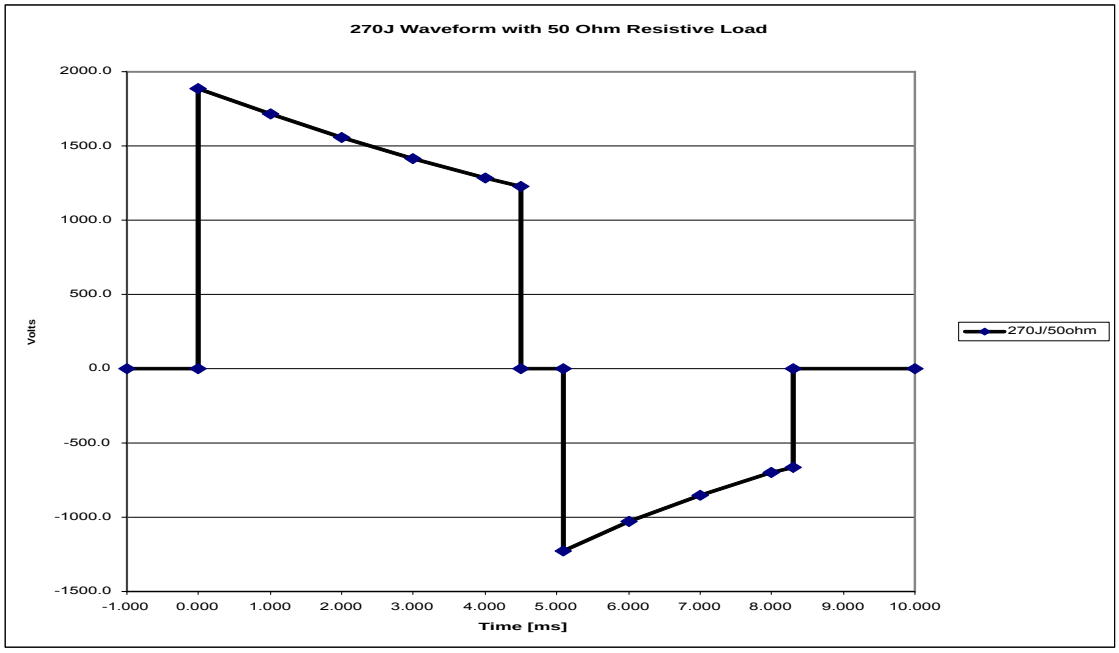
STAR Biphasic Waveform – 50J into internal spoon

Table B – 50J Waveform into Different Resistive Loads (Typical Values)

Patient's Impedance (Ohms)	Phase 1 Delivered Start Volts	Phase 1 Delivered End Volts	Phase 1 Duration (ms)	Phase 2 Delivered Start Volts	Phase 2 Delivered End Volts	Phase 2 Duration (ms)	Total Energy Delivered (J)
10	573V	217V	3.00ms	217V	27V	3.2ms	47J
20	697V	386V	3.00ms	386V	108V	3.2ms	51J
25	728V	426V	3.25 ms	426V	147V	3.2ms	52J
50	800V	531V	4.50 ms	531V	294V	3.2ms	50J
75	828V	576V	5.75ms	576V	382V	3.2ms	47J
100	842V	600V	7.00 ms	600V	437V	3.2ms	45J

ENERGY LEVELS AND PATIENT IMPEDANCE

The Biphasic Truncated Exponential (BTE) waveform delivers energy that is variant with the patient impedance. The waveform is designed to deliver the selected energy when the patient impedance is 50 Ohms, as shown in the above waveform table.



SAFETY STANDARDS AND COMPLIANCE REQUIREMENTS

The Responder 2000 is designed to meet all applicable requirements of the standards listed below.

IEC 60601-1, (1988 + A1:1991 + A2:1995), Medical Electrical Equipment Part 1 General Requirements for Safety

EN 60601-1, (1990 + A1:1993 + A2:1995), 2nd Edition Medical Electrical Equipment, Part 1: General Requirements for Safety

IEC 60601-1-1, (2000), Medical Electrical Equipment - Part 1: General Requirements for Safety 1: Collateral Standard: Safety Requirements for Medical Electrical Systems

IEC 60601-2-4, (2002), Medical Electrical Equipment – Part 2-4: Particular Requirements for the Safety of Cardiac Defibrillators

IEC 60601-2-49, (2001), Medical Electrical Equipment - Part 2-49: Particular Requirements For The Safety Of Multifunction Patient Monitoring Equipment

IEC 60601-2-27, (1994), Medical electrical equipment, part 2: Particular requirements for the safety of electrocardiographic monitoring equipment

UL 60601-1, (2003), Medical Electrical Equipment Part 1, General Requirements for safety

CAN/CSA-C22.2 No. 601.1-M90, Medical electrical equipment Part 1: General Requirements for Safety

ANSI/AAMI EC-13-2002, Cardiac monitors, heart rate meters, and alarms

ANSI/AAMI DF80-2003, Medical Electrical Equipment – Part 2-4: Particular Requirements for the Safety of Cardiac Defibrillators (including automated external defibrillators)

ELECTROMAGNETIC COMPATIBILITY REQUIREMENTS

The Responder 2000 meets the requirements of the following EMC standards, as required by IEC 60601-2-4.:

IEC 60601-1-2 (2001), Medical electrical equipment Part 1: General requirements for safety 2. Collateral standard: electromagnetic compatibility - Requirements and tests.

EMISSIONS

Electromagnetic Fields: CISPR 11 (2003), Industrial, scientific and medical (ISM) radio-frequency equipment - radio disturbance characteristics - limits and methods of measurement; Group 1, Class B. IEC 60601-2-4 (2002), Section 36.201.1.

Harmonic distortion: IEC 61000-3-2 (2004), Electromagnetic Compatibility (EMC) Part 3-2: Limits - Limits For Harmonic Current Emissions (Equipment Input Current Less Than Or Equal To 16 A Per Phase).

Voltage fluctuations and flicker: IEC 61000-3-3 (2002), Electromagnetic Compatibility (EMC) - Part 3-3: Limits - Limitation Of Voltage Changes, Voltage Fluctuations And Flicker In public Low-Voltage Supply Systems, For Equipment With Rated Current Less Than Or Equal To 16 A Per Phase.

IMMUNITY

Electromagnetic: IEC 61000-4-3 (2003), Electromagnetic compatibility (EMC) - part 4-3: Testing and measurement techniques - radiated, radio-frequency, electromagnetic field immunity test; Level 3 (10V/m) and X (20V/m). IEC 60601-2-4 (2002) Section 36.202.3.

Magnetic: IEC 61000-4-8 (1994), Electromagnetic compatibility (EMC) - part 4. Testing and measurement techniques - section 8. Power frequency magnetic field immunity test basic EMC publication; Level X (3 A/m). IEC 60601-2-4 (2002), Section 36.202.8.

ESD: IEC 61000-4-2 (2001), Electromagnetic compatibility (EMC) - part 4-2: testing and measurement techniques - electrostatic discharge immunity test; Level 3. IEC 60601-2-4 (2002), Section 36.202.2.

Conducted: IEC 61000-4-6 (2003), Electromagnetic compatibility (EMC) - part 4-6: testing and measurement techniques - immunity to conducted disturbances, induced by radio-frequency fields. IEC 60601-2-4 (2002), Section 36.202.6.

Fast transients and bursts: IEC 61000-4-4 (2001), Electromagnetic compatibility (EMC) - part 4: Testing and measurement techniques - section 4: Electrical fast transient/burst immunity test. IEC 60601-2-4 (2002), Section 36.202.4.

Surges: IEC 61000-4-5 (2001), Electromagnetic compatibility (EMC) - part 4: Testing and measurement techniques - section 5: Surge immunity test. IEC 60601-2-4 (2002), Section 36.202.5.

Voltage dips, short interruptions and voltage variations on power supply input lines: IEC 60601-4-11 (2004), Electromagnetic Compatibility (EMC) - Part 4-11: Testing And Measurement Techniques - Voltage Dips, Short Interruptions And Voltage Variations Immunity Tests.

ENVIRONMENTAL STANDARDS

SHOCK AND VIBRATION

The Responder 2000 is tested per the following when in the unpackaged condition:

Bump: IEC 60068-2-29 (1987), Test EB: bump; 25g, 6 ms, 0.9 m/s ΔV, and 1000 bumps in each direction

Sine Vibration: IEC 60068-2-6 (1995), Environmental testing - part 2. tests - test FC: Vibration (sinusoidal); 0.15mm displacement amplitude, 10-55Hz, 10 sweep cycles in each axis

Random Vibration: IEC 60068-2-64 (1993), Environmental testing - part 2: test methods - test FH: Vibration broadband random (digital control) and guidance: 1-100Hz, 0.01g2/Hz 30 minutes.

Free Fall Drop: IEC 60068-2-32 (1975 + A1:1990), Environmental testing - test methods - test ED: free fall; 18 inches

Enclosure Protection: IEC 60529 (2003), Degrees of protection provided by enclosures (IP code); IP22.

STORAGE AND SHIPPING

When packaged in the shipping container, the Responder 2000 meets the requirements of:

ISTA Preshipment Test 2A (2001), Simulation Performance Test Procedure - Packaged-Products 150lb(68 kg) or Less

ELECTROMAGNETIC EMISSIONS TABLE

Guidance and manufacturer's declaration – electromagnetic emissions		
The Responder 2000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Responder 2000 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Responder 2000 uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Responder 2000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

ELECTROMAGNETIC IMMUNITY TABLE

Guidance and manufacturer's declaration – electromagnetic immunity			
The Responder 2000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Responder 2000 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Responder 2000 requires continued operation during power mains interruptions, it is recommended that the Responder 2000 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Responder 2000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Responder 2000 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Responder 2000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 Vrms	d = 1.2 √P
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	10 Vrms	d = 1.2 √P
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RESPONDER 2000 is used exceeds the applicable RF compliance level above, the RESPONDER 2000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RESPONDER 2000 .

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

RF COMMUNICATIONS TABLE

Recommended separation distances between portable and mobile RF communications equipment and the Responder 2000

The RESPONDER 2000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RESPONDER 2000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RESPONDER 2000 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 to 40.70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

EN 60601-1-2 COMPLIANCE

WARNING: RF Interference
Known RF sources, such as cell phones, radio or TV stations, and two-way radios, may cause unexpected or adverse operation of this device. Consult qualified personnel regarding system configuration.

WARNING: Equipment Configuration
The equipment or system should not be used adjacent to, or stacked with other equipment. If adjacent or stacked use is necessary, test the equipment or system to verify normal operation. Refer to the Electromagnetic Immunity information in the appendix.

COMPLIANT CABLES AND ACCESSORIES

WARNING:
The use of accessories, transducers and cables other than those specified in Section 7 of this manual may increase emissions or decrease immunity performance of the device/system.

The table below lists cables, transducers, and other applicable accessories with which GE Medical Systems claims EMC compliance.

NOTE: Any supplied accessories that do not affect EMC compliance are not included.

Part Number	Description	Maximum Lengths
ECG Cables and Lead wire set		
2017003-001	IEC 5 lead ECG cable	3.6 m / 12 ft
2017003-003	AHA 5 lead ECG cable	3.6 m / 12 ft
414556-001	5 lead wire set AHA	0.74m / 29 inch
414556-003	5 lead wire set IEC	0.74m / 29 inch
2021141-001	3 lead wire set IEC , combined cable and lead wire	4.8 m / 16 ft
2021141-002	3 lead wire set AHA , combined cable and lead wire	4.8 m / 16 ft
Defibrillator Cables		
2030247-001	Cable for defibrillator electrode pads	4 m / 13 ft
2030249-001	Cable for defibrillator contact paddle, with handle	4 m / 13 ft
SPO_2 Cables and Sensors		
OXY-ES3	OxyTip+® interconnect cable	3 m / 10 ft
OXY-F-UN	Finger Sensor	1 m / 3.3 ft
OXY-E-UN	Ear Sensor	1 m / 3.3 ft
OXY-W-UN	Wrap Sensor	1 m / 3.3 ft
Power cords		
2019204-007	Power cord, North America	2.5 m / 8 ft
2020387-002	Power cord, Europe	2.5 m / 8 ft

2020387-003	Power cord, Argentina	2.5 m / 8 ft
2020387-004	Power cord, Denmark	2.5 m / 8 ft
2020387-005	Power cord, India & South Africa	2.5 m / 8 ft
2020387-006	Power cord, Italy	2.5 m / 8 ft
2020387-007	Power cord, Japan	2.5 m / 8 ft
2020387-008	Power cord, Switzerland	2.5 m / 8 ft
2020387-009	Power cord, UK	2.5 m / 8 ft
2020387-010	Power cord, Israel	2.5 m / 8 ft
2020387-011	Power cord, Australia	2.5 m / 8 ft

SECTION 7: ACCESSORIES

OVERVIEW

This section contains a list of parts and accessories for Responder 2000. To place an order, contact your representative or distributor.

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RESPONDER 2000 ACCESSORIES

Responder 2000 is available in more than twenty languages, with others being added on a regular basis. For a complete list of those available, contact your sales representative or Customer Service.

WARNING: The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the equipment.

ECG CABLES AND LEAD WIRE SETS

Part Number	Description
2017003-003	IEC 5-lead ECG cable, 12 ft
2017003-001	AHA 5-lead ECG cable, 12 ft
414556-001	5-Lead wire set AHA 29-inch
414556-003	5-Lead wire set IEC 29-inch
412682-001	3-Lead wire set AHA 29-inch
412682-003	3-Lead wire set IEC 29-inch
2021141-002	IEC 3-lead wire set, combined cable and lead wire
2021141-001	AHA 3-lead wire set, combined cable and lead wire

ECG ELECTRODES

Part Number	Description
2014786-001	ECG electrodes, rectangular, foam, ten (10) 30-electrode pouches

DEFIBRILLATOR CABLES, PADDLES AND PADS

Part Number	Description
2030247-001	Cable for defibrillation electrode pads
850/40156/025	Adult electrodes, 25 pairs
850/40156/005	Adult electrodes, 5 pairs
850/40518/025	Child electrodes, 25 pairs
850/40518/005	Child electrodes, 5 pairs
2030249-001	Contact paddle cable, with handle, internal, 4 m
38401319	Contact paddle, internal, for adult, 1 pair
38401320	Contact paddle, internal, for children, 1 pair
38401321	Contact paddle, internal, for infant, 1 pair
2030137-001	External paddles with two (2) adult surface plates
2030134-001	Replacement Adult surface plates for part number 2030137-001

ECG ACCESSORY KITS

Part Number	Description
2025269-007	3-lead Accessory Kit, AHA
2021141-001	Multi-Link 3-Lead ECG Cable with Integrated Grabber Leadwires, AHA, 12 ft (3.6m) 60-mm thermal paper (1 roll; 1/50 of 2026327-001) ECG Electrodes; round, foam (one (1) 30-electrode pouch); 1/10 of 2014786-001
2025269-008	5-lead Accessory Kit, AHA
2017003-001 414556-001	Cable, ECG, Multi-Link 5-Ld Standard, AHA, 12 ft. (3.6 m) 5-Lead wire set AHA, 29-inch (74 cm) 60-mm thermal paper (1 roll; 1/50 of 2026327-001) ECG Electrodes; round, foam (one (1) 30-electrode pouch); 1/10 of 2014786-001
2025269-009	3-lead Accessory Kit, IEC
2021141-002	Cable, ECG, Multi-Link 3-Ld Integrated Grab Ldwr, IEC, 12 ft. (3.6 m) 60-mm thermal paper (1 roll; 1/50 of 2026327-001) ECG Electrodes; round, foam (one (1) 30-electrode pouch); 1/10 of 2014786-001
2025269-010	5-lead Accessory Kit, IEC
2017003-003 414556-003	IEC 5-lead ECG cable, 12 ft 5-lead wire set IEC 29-inch (74 cm) 60-mm thermal paper (1 roll; 1/50 of 2026327-001) ECG Electrodes; round, foam (one (1) 30-electrode pouch); 1/10 of 2014786-001

SPO_2 CABLES AND SENSORS

Part Number	Description
OXY-F-UN	Datex-Ohmeda sensor, finger, reusable
OXY-ES3	Datex-Ohmeda cable
OXY-E-UN	Datex-Ohmeda sensor, ear
OXY-W-UN	Datex-Ohmeda sensor, wrap
OXY-RTW	Datex-Ohmeda replacement wide adhesive tape, 100 count
OXY-RWL	Datex-Ohmeda replacement large foam wrap, 24 count

POWER CORDS

Part Number	Description
2019204-007	Power Cord, North America
2020387-002	Power Cord, Europe
2020387-003	Power Cord, Argentina
2020387-004	Power Cord, Denmark
2020387-005	Power Cord, India & South Africa
2020387-006	Power Cord, Italy
2020387-007	Power Cord, Japan
2020387-008	Power Cord, Switzerland
2020387-009	Power Cord, UK
2020387-010	Power Cord, Israel
2020387-011	Power Cord, Australia

OTHER ACCESSORIES

Part Number	Description
2025267-001	Rechargeable battery, GE-branded
2027556-001	Battery charger with North American power cord
2027556-002	Battery charger with European power cord
2027556-003	Battery charger with Argentina power cord
2027556-004	Battery charger with Denmark power cord
2027556-005	Battery charger with India & South Africa power cord
2027556-006	Battery charger with Italy power cord
2027556-007	Battery charger with Japan power cord
2027556-008	Battery charger with Switzerland power cord
2027556-009	Battery charger with UK power cord
2027556-010	Battery charger with Israel power cord
2027556-011	Battery charger with Australian power cord
2026327-001	60-mm thermal paper, fifty (50) rolls
2025269-003	Symbio CS 301 Pacer Tester
2025269-005	Unit Bag
2025269-006	Accessory Bag (Fits inside Unit Bag)
2025653-049	ECG Sync Cable
9812-014	Signa Conductive Defib Gel, twelve (12) 250-gm tubes
2025269-004	Adaptor plate for mounts
407349-009	Wall mount
2007059-001	Crash-cart mount

SECTION 8: CONTACT INFORMATION/CUSTOMER SERVICE

OVERVIEW

This section contains a list of parts and accessories for Responder 2000. To place an order, contact your representative or distributor.

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CONTACT INFORMATION / CUSTOMER SERVICE

To order supplies or accessories, contact your representative or distributor. For technical support, contact your local GE customer service.
Please have the serial and model numbers available. The serial and model numbers are located on the back of the Responder 2000.

Responder 2000 is manufactured by:

Manufacturing:
Cardiac Science Corporation
500 Burdick Parkway
Deerfield, WI 53531, USA

Authorized European Representative:
MDSS GmbH
Schiffgraben 41
D-30175 Hannover
Germany
Tel: +49 511 62 62 86 30
Fax: +49 511 62 62 86 33

CE 0086

Responder 2000 is manufactured for:

GE Medical Systems Information Technologies, Inc.
8200 West Tower Avenue, Milwaukee, WI 53223 USA
Tel.: 1 414 355 5000
+800 558 5120 (USA only)
Fax: +1 414 355 3790

GE Medical Systems Information Technologies GmbH
Munzinger Str. 3, D-79111 Freiburg, Germany
Tel.: +49 761 4543 0
Fax: +49 761 4543 233

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Responder™ 2000

defibrillator/monitor